The Rehabilitation Needs of Women with Metastatic Breast Cancer

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Now there is grief the couturier, and grief
The needlewoman mourning with her hands,
And grief the scattered finery of life,
The clothes she gave as keepsakes to her friends.

(from "Empty Wardrobes" by
Douglas Dunn in "Elegies")

DECLARATION

I declare that this thesis was composed by myself and that all data were collected and analysed by myself.

Signature **C.L. Fulton**

Date 27th October 1992.

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ABSTRACT

Each year approximately 26,000 British women develop breast cancer and 16,000 die from their disease. Breast cancer is the most common cancer in women in the United Kingdom. Previously, most studies have focused on the needs of women following surgery for the treatment of primary breast cancer. However, few systematic studies have monitored the needs of women with metastatic disease. The median survival of women with metastatic breast cancer is 19 months and therefore it would seem appropriate to monitor the rehabilitation needs of these women.

This study examines the physical, psychological, and social rehabilitation needs of a consecutive series of 80 patients following definitive diagnosis of metastatic breast cancer. These patients were interviewed every eight weeks at home on eight separate occasions and were asked to complete the following standardised questionnaires: The Cancer Rehabilitation Evaluation System (CARES); The Hospital Anxiety and Depression Scale (HAD); and The Rotterdam Symptom Checklist (RSCL). In addition, the researcher completed an interview schedule to detail demographic details, current treatment, and which members of the medical team the patient had seen in the previous month. The researcher also completed the Edinburgh Rehabilitation Status Scale (ERSS) which gives a total score of disability.

The results of the descriptive component demonstrated that patients had a range of different rehabilitation needs throughout the course of their illness as defined by the CARES and the ERSS. These needs do not change throughout the course of the metastatic phase of the disease but detection of these problems is extremely low and, as a result, referral to appropriate services does not usually occur. Demographic factors such as age, marital status, social class, and number and age of children were not found to be associated with rehabilitation status. A significant problem in this group of patients was found to be that of mood disturbance and a complex inter-relationship was found to exist between rehabilitation status, age, physical symptomatology and mood using multiple stepwise regression analyses and factor analysis.

In addition, a small pilot intervention study was carried out to evaluate a method of detecting and referring patients with rehabilitation needs

through the intervention of a "rehabilitation co-ordinator". Seventeen consecutive patients were recruited to this pilot study and were randomised to either the "intervention" (n-10) or "control" group (n=7). Patients were interviewed on four occasions using the same standardised questionnaires as those in the main descriptive study, and the results demonstrated that there were no significant differences between the two groups in terms of the following: rehabilitation status; mood; physical symptomatology; and contact with multidisciplinary team members. However, patients in the intervention group displayed high levels of satisfaction with the rehabilitation co-ordinator service perceiving it as having improved their quality of life.

The results of both studies are discussed in the context of previous research and future research directions are examined. The role of the "rehabilitation co-ordinator" in cancer care is discussed and recommendations are made regarding further evaluation and implementation of this concept.

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Chapter One

EPIDEMIOLOGY AND TREATMENT OF CANCER OF THE BREAST

Introduction

Breast cancer, like any disease, consists of various stages: diagnosis, primary treatment, adjuvant treatment, recurrence and palliation. In order to understand the rehabilitation needs of women with metastatic breast cancer, it is necessary to understand the epidemiology and treatment of cancer of the breast as patients may have previously had many types of treatment which may have lasted many months. This Chapter will therefore outline the epidemiology and treatment for cancer of the breast.

DESCRIPTIVE EPIDEMIOLOGY

Breast cancer is the commonest malignant tumour affecting women in the U.K., with approximately 26,000 women being diagnosed each year and 16,000 women dying from it [Cancer Research Campaign, 1991]. In the U.K. it is estimated that 1 out of 12 women will develop breast cancer in her lifetime [Cancer Research Campaign, 1991]. The median age of the patients with breast cancer is 55 with about one third of all cases appearing before 50. Recently however there appears to be an increasing number of cases among young women in their 20's and 30's [Khafif, 1986]. Breast cancer accounts for 19 per cent of all new cases of female cancer, whereas breast cancer in men is a rare cancer with approximately 175 cases and 90 deaths occurring annually in the U.K. [Cancer Research Campaign, 1991].

World-wide, it was estimated by Parkin et al [1988] that in 1980 over half a million women were first diagnosed as having breast cancer. The implications of these facts are clear in that breast cancer poses an important public health concern. Considerable world-wide attention has been focused in attempting to discern trends in the epidemiology of breast cancer. In a review of the literature regarding the descriptive epidemiology of breast cancer Boyle [1988] writes:

> "different populations throughout the world experience different levels of breast cancer and these levels change with

time. Within countries, breast cancer rates vary among racial groups, by socio-economic status, among religious groups..... When migration takes place, groups of migrants tend to acquire the breast cancer pattern of their new home.....For reasons such as these, it is believed that environmental factors, rather than genetic factors, are of paramount importance in the aetiology of breast cancer: 'environment' being defined in its broadest sense to include a wide range of factors such as dietary, social and cultural practices."[Boyle, 1988, p 21]

ANALYTICAL EPIDEMIOLOGY

As a result of the structure and function of the human breast, it is evident that there is a close link between ovarian function and production of breast growth: at puberty ovarian secretion of oestrogen and progesterone stimulates growth of the breast. This link has also led to the hypothesis that there is a link between tumour growth in breast cancer and hormone activity. Therefore many studies have focused on related factors e.g. menarche, menopause, and childbirth where there is alteration of hormonal balance. In addition, studies have been conducted monitoring the effects of oral contraceptives and hormone therapy.

This section will accordingly be sub-divided to deal with each of the above.

(a) The relation of age at menarche and breast cancer.

The findings of studies monitoring the potential relationship between age at menarche and incidence of breast cancer vary considerably. It has been reported [Bucalossi and Veronesi, 1959; Henderson et al, 1974; Herity et al, 1975] that age at menarche was slightly younger in breast cancer patients compared with a control group.

However this relationship has been shown not to be significant in other studies. Interestingly all studies referred to above were retrospective studies which could account for the apparently contradictory findings. In more recent prospective studies [Tulinius et al, 1978] the findings supported the relationship between early age at menarche and incidence of breast cancer.

(b) Age at first full-term pregnancy.

MacMahon et al [1970] supported the view that there is an inverse relationship between parity and the risk of breast cancer. In addition, it was shown that the age of first full term pregnancy relates to the risk of breast cancer. The protective role of parity however is only apparent in those women who give birth before the age of 32.

(c) Menopause.

It has clearly been demonstrated that a late age at menopause is associated with increased incidence of breast cancer. The risk factor can be set out as follows:

> "risk of 1.00 in group with menopause 45-55 years
> risk of 0.73 in group with menopause before 45 years
> risk of 1.48 in group with menopause over 55 years."
> [Trichopoulous et al 1972, p 609].

In addition artificial menopause as a result of oophrectomy reduces the risk of breast cancer.

(d) Use of contraceptive pill.

Theoretically it would be possible that prolonged use of oestrogens and progesterones may increase the risk of breast cancer. Many studies have been conducted to see whether this is the case. However, to date, the results of this research are inconclusive.

(e) Other factors related to breast cancer.

De Waard et al [1977] investigated the correlation between weight and the risk of breast cancer. They found that there is a correlation between increased risk of breast cancer with overweight people. However, it was unclear from this and other studies whether this was due to body fat or weight *per se*. Studies of rodents fed on a high fat diet has shown that they have an increased risk of breast cancer. However this has not been demonstrated conclusively with humans.

Family history of breast cancer is also relevant. Women with a female relative who has had breast cancer have a risk two to three times that of

the general population. Other studies have shown that the risk is greatest for women with a first-degree relative with bilateral or premenopausal breast cancer [Cady 1970; Anderson 1977].

Conclusion

The main factors related epidemiologically to breast cancer appear to relate to menstrual and reproductive history. It has to be noted however that these are factors related to breast cancer but the actual cause of breast cancer, and hence prevention, is as yet unknown [Denton, 1989].

PATHOLOGICAL VARIETIES OF BREAST CANCER

The most commonly adopted histological classification of breast cancer is that of the World Health Organisation [1981]. According to this, malignant epithelial tumours are made up of three types: a/ non-invasive tumours; b/ invasive tumours of several types; c/ Paget's disease of the nipple. The majority of breast cancers are invasive ductal carcinomas followed by invasive lobular carcinomas.

The significance of histopathological findings is emphasised by many research studies. For example, Silverberg and Chitale [1973] suggested that tumours with a large intraductal component have a better prognosis. A retrospective study conducted by Rilke et al [1978] revealed that the vast majority of cases of cancer of the breast (80 per cent) fall into the group with the worst prognosis. For example the 30 year survival rate of patients with invasive lobular and ductal carcinoma was reported to be 34 per cent and 29 per cent respectively. However, the 30 year survival rate for patients with the more rare papillary carcinoma was 65 per cent.

PRE-OPERATIVE ASSESSMENT OF BREAST CANCER

Patients most commonly present with a lump in the breast [McKinna, 1983]. Traditionally patients with a breast lump either had a frozen section of a sample obtained through open biopsy and mastectomy immediately followed in the same operation if cancer was confirmed, or alternatively patients underwent excisional biopsy followed several days later by mastectomy if cancer was diagnosed. Nowadays, the more standard preoperative procedure to confirm cancer is mammography, ultrasound and fine needle aspiration cytology of the breast lump and, if there is suspected node involvement, the node will be aspirated for cytological investigation. Malberger et al [1981] demonstrated that this approach greatly increases the accuracy of diagnosis.

In addition, patients are clinically staged following definitive diagnosis of cancer of the breast. The system of staging which has been widely adopted is the TNM (Tumour Node Metastases) staging system. This system was developed over 35 years ago and the rules governing this system have been clearly set out in a handbook published by the Union Internationale Contre le Cancer [UICC, 1978]. This system of staging has replaced the system formerly used which was the Manchester classification. Both of these are detailed below:

Figure 1 : Staging systems in breast cancer

Manchester staging system	Description
Stage 1	Breast alone involved +/- overlying skin
Stage 2	Breast as for Stage 1 and axillary nodes involved
Stage 3	Skin invaded, fixed or ulcerated, or tumour fixed to underlying muscle or pectoral fascia
Stage 4	Fixed axillary lymphadenopathy, supraclavicular involvement and/or distant metastases
TNM Staging Notation for Breast Cancer	**Description**
T1	Tumour less than 2cm in diameter
T2	Tumour 2-5cm in diameter
T3	Tumour >5cm
T4	Tumour of any size with direct extension to chest wall or skin
N0	No palpable lymph node involvement
N1	Mobile ipsilateral nodes
N2	Fixed ipsilateral nodes
N3	Supraclavicular nodes or infraclavicular nodes or oedema of the arm
M0	No distant metastases
M1	Distant metastases

[Souhami and Tobias, 1986, p 229]

The characteristics of the primary tumour, the presence or absence of axillary lymph node involvement, and the presence or absence of distant metastases are detailed in these systems of staging. Patients therefore undergo chest X-rays, a bone scan, a liver ultrasound and various blood tests to ascertain the stage of the disease. These staging characteristics are strongly correlated with survival. In addition the hormone receptor status of the biopsy sample of breast and lymph gland tissue is established because some breast cancer cells have receptors for oestrogen and other hormones. The tumour is then classified as oestrogen receptor (ER) positive or negative. Evidence suggests that tumours which are ER positive are more likely to respond to hormone treatment, and those which are ER negative rarely respond. Post menopausal women commonly are ER positive (65 per cent) and only 30 per cent of pre menopausal women have a positive ER status [Souhami et al 1986].

SURGICAL MANAGEMENT OF PRIMARY BREAST CANCER

It is only within the last two decades that there is now some debate surrounding the choice of operation in patients with early breast cancer. Up until that time the approach to the management of breast cancer was apparently straightforward: the standard approach involving a radical mastectomy or in some instances an extended radical mastectomy. The use of the Halstedian radical mastectomy was based on the hypothesis that breast cancer can be divided into three distinct stages: (1) a local phase where the tumour is completely confined to the breast; (2) a phase of regional extension in which there is involvement of the draining lymph nodes; (3) and finally a phase where the tumour is widely disseminated.

It seemed, according to this hypothesis, that patients in the first and second "stage" could be cured by operation. The technique of such operations was to remove the tumour and the breast tissue which would be at risk of lymphatic infiltration and removal of the draining lymph nodes.

However, the hypothesis behind such operative procedures has been called into question. A new hypothesis suggested by Veronesi et al (1981) proposes that breast cancer is often systemic even before an initial diagnosis of breast cancer is made. The implication of such an hypothesis would be that despite the extensive nature of such surgical techniques as the Halstedian radical mastectomy they would fail ultimately to control the disease as by that time the disease was already disseminated. The time at which overt metastases appeared would be dependent upon the tumour burden, growth rate and other biological factors.

The choice of surgical treatment for a resectable primary breast cancer depends on several factors:

(1) the site, size and clinical features of the tumour;

(2) the clinical status of the axillary lymph nodes;

(3) the patient's age and general fitness; and when excisional biopsy has been performed:

(4) the histological appearance of the sample;

(5) the oestrogen receptor status and growth rate of the excisional biopsy sample.

Radical Mastectomy

The classical operation of radical mastectomy was introduced by Halsted in 1894 and was based upon an anatomical approach. It was thought at this time that lymphatic spread was of prime importance and the radical mastectomy "ensured" local control by removing the breast and all the primary lymphatic channels. Thus, in this procedure *en bloc* dissection of the whole breast, with division of pectoralis major and minor muscles and contents of the axilla is carried out. In order to achieve total clearance a large incision is required and there remains a considerable loss of contour.

The morbidity associated with radical mastectomy is high causing arm swelling (lymphoedema), deformity (causing body image problems), and wound healing problems.

Extended Radical Mastectomy

As a result of findings that other lymph nodes than axillary ones were frequently involved with tumour it seemed to suggest that not even the radical mastectomy was extensive enough. Hence an extended radical mastectomy was introduced in 1949 where additional dissection of the internal mammary nodes was carried out. However the results of a multi-centre prospective study where patients were randomised to undergo either a radical or extended radical mastectomy failed to demonstrate significant differences in terms of relapse free interval and overall survival.

Modified Radical Mastectomy

This procedure which was chiefly ignored in the USA for 20 years has now replaced the radical mastectomy as the standard operative procedure in the USA. This procedure leaves the pectoralis major intact but removes the breast, pectoralis minor and axillary contents.

Total (simple) Mastectomy

McWhirter (1948) advocated a resection from the clavicle to the costal margin and from the midline to the latissimus dorsi. The axillary nodes are not removed in this procedure because McWhirter believed "when the disease is confined to the breast: (1) dissection of the axilla is unnecessary; (2) when the tumour has spread to the axillary nodes, radical mastectomy frequently will fail because occult metastases may be present in the supraclavicular nodes that are beyond the surgical dissection but which can be eradicated by radiation therapy; (3) radical mastectomy alone cannot influence the course of the disease in patients in whom metastases to the internal mammary nodes might disseminate the disease; and (4) oedema of the arm would not occur as frequently following the less radical procedure" [Harris et al 1985, p 1137].

Hence McWhirter advocated total mastectomy combined with post operative radiotherapy in the treatment of primary breast cancer.

Partial Mastectomy

Mastakallio [1954] advocated simple removal of the tumour and administering post-operative radiotherapy in cases when there were no palpable lymph nodes in the axilla and when the primary breast tumour was no larger than a "hen's egg". This procedure of partial mastectomy is also referred to as segmental mastectomy, local excision, lumpectomy or tylectomy.

Wide local excision is a conservative surgical treatment of breast cancer and involves local excision of the tumour achieving an excisional margin of 1-2 cm. This procedure can also be accompanied by axillary node clearance where the nodes have been clinically staged as having tumour cells present.

In recent years the less radical operations have been widely adopted. Many clinical research trials have been carried out to evaluate the various techniques and compare the interval between initial diagnosis and recurrence (disease-free interval) and survival. However, as a result of the methodological shortcomings in the early studies many of the results cannot be compared as often the studies were non-randomised and the selection criteria were vague. However, a recent National Surgical

Adjuvant Breast Project (NSABP) Study of 1665 patients followed up for ten years showed that there is no evidence that a simple mastectomy is less effective than a Halsted radical mastectomy [Fisher et al, 1977]. In addition, a study by Veronesi et al [1981] carefully selected patients with tumours staged as T1N0 and treated them with quadrantectomy and irradiation. This and other similar studies strongly supported the argument that segmental resection with irradiation is as effective as total mastectomy and radical mastectomy.

The important conclusion to be drawn from these studies is that breast cancer does not undergo a logical pattern of dissemination. Instead it supports Veronesi's hypothesis that dissemination in the form of distant micrometastases are present before initial surgery is carried out.

Reconstructive surgery after mastectomy

Nowadays, patients are encouraged to play an active role in the decision-making process regarding the treatment adopted. An important issue to the woman is how she will look after surgery and to this end many women are offered reconstructive surgery i.e. surgery to attempt to reconstruct the breast to attain the "normal" contour of the breast. This surgery may be carried out at the same time as mastectomy, or may be carried out as a secondary procedure. Breast reconstruction may adopt silicone implants which are embedded in a myocutaneous flap. This flap is made up of skin, subcutaneous tissue and muscle and the flap is transferred or "swung round" on a pedicle to cover the breast. The myocutaneous flap most commonly used is that of latissimus dorsi. Some women may be content to have only the contour of the breast achieved. However in the event of some women wanting "complete" restoration of the breast they may be offered nipple reconstruction. A recent advance in breast reconstruction is the use of tissue expanders. During mastectomy an expander is implanted under the skin on the chest wall. Over many weeks following surgery a small volume of normal saline solution is injected through a valve which fills the expander gradually. This procedure depends on the elasticity of the skin and many patients find the tightness of the skin caused by the tissue expander uncomfortable. A second operation is required once symmetry with the other breast has been achieved in order to remove the tissue expander and insert a silicone implant. Many patients however decline reconstructive surgery and

instead choose to use a prosthesis which is contained in the brassiere.

RADIOTHERAPY IN THE PRIMARY MANAGEMENT OF BREAST CANCER

In 1927 the first patients were treated in Germany adopting tumour excision followed by radium treatment. In 1939 Peters commenced a research study to monitor the effectiveness of local excision and radiotherapy. She matched each patient involved in the study with a "control" patient who underwent radical mastectomy and included in the matching was age, and size of primary tumour. In 1977 the results were published [Peters, 1977] and there was not a statistically significant difference between the two groups regarding survival and disease-free interval.

A large randomised study by Veronesi [1981] gave more weight to this approach. Patients in this study (n=701) had primary breast cancer where the tumour measured less than 2cm and there were no palpable lymph nodes. Similar to the findings of Peters study, no difference was found in terms of local recurrence, overall survival or disease-free interval between matched patients who had quadrantectomy and radiotherapy or radical mastectomy.

Many studies have been conducted to monitor the effectiveness of radiation therapy given as an adjuvant to primary surgery (simple mastectomy to radical mastectomy). These have shown consistent results over the last thirty years that irradiation reduces the risk of locoregional relapse, but has no effect of distant disease free survival. Most importantly there is no effect on overall survival. When radiotherapy is used in conjunction with surgery it is not administered until the wound has healed. The breast, the chest wall and regional lymph nodes are irradiated. Commonly the dose given is between 40-50Gy given daily over five weeks. Following this the patient may receive a "booster" dose to the tumour site and this may be achieved by conventional methods or through a radioactive implant. These implants consists of fine perspex tubes which are inserted through the breast at the tumour site. The tubes are then loaded with radioactive material, commonly irridium. The tubes are removed after the dose has been given.

ADJUVANT THERAPY

(a) Chemotherapy

The use of chemotherapy has made a major impact on the survival of patients with testicular cancer, leukaemia and lymphoma. However there appears to be a degree of controversy regarding the value of adjuvant chemotherapy in the treatment of breast cancer, particularly when there is no evidence of active systemic disease [Keane et al, 1990]. The debate concerns the issue of whether chemotherapy improves survival, or whether it prolongs the remission free interval, or whether the advantages are merely the result of ovarian oblation secondary to the use of cytotoxic agents.

The National Surgical Adjuvant Breast Project (NSABP) carried out research to monitor the effectiveness of a number of single agent and combination chemotherapies. To date, 10,000 patients have been included in this study. The most encouraging results in both disease free intervals and decreased mortality appeared to be related to those women who were premenopausal with positive nodes and were treated with adjuvant melphalan or melphalan with 5 fluorouracil [Harris et al, 1985]. Bonnadonna compared adjuvant CMF (cyclophosphamide, methotrexate and 5 fluorouracil) with a control group and showed improved survival in the treated group, and this was most marked in premenopausal women with more than three axillary nodes involved. Based on the Milan trial the following conclusions have been argued [Bonnadonna et al, 1985]:

(1) Post menopausal women with Stage 2 breast cancer do not benefit in terms of overall survival from adjuvant CMF.

(2) Premenopausal women with axillary node involvement benefited in terms of relapse free survival from adjuvant CMF. The number of nodes involved in these women was significant. In those premenopausal women with one to three histologically positive nodes the relapse free survival was 61 per cent compared with the control 40 per cent and overall survival 68 per cent compared with the control 51 per cent. For those patients with four to ten nodes involved there was a significant improvement in disease free survival, although this was not the case in overall survival.

(b) Adjuvant endocrine therapy of breast cancer

Hormonal therapy used as a prophylactic measure in the adjuvant treatment of primary breast cancer is not new. In 1889 Schinzinger first proposed it and in 1905 De Courmelles proposed ovarian irradiation as an alternative to surgical removal of the ovaries. The National Surgical Adjuvant Breast Project Group [Fisher et al, 1968] commenced a trial of surgical oophrectomy in 1961 with premenopausal women younger than 50 years. All patients underwent radical mastectomy and were randomised to one of three post operative treatment groups: oophrectomy; thiotepa; or a placebo. The results showed that there were no significant differences between the treatment groups in terms of survival. Oophrectomy is seldom carried out nowadays in patients with primary cancer of the breast. This is due to the dubious effectiveness in terms of overall survival. In addition, alternative endocrine treatments in the form of antioestrogens have been found to be of use in patients with breast cancer.

(c) Adjuvant Tamoxifen

Despite the poor results yielded from such studies looking at oophrectomy, many encouraging studies have been carried out looking at Tamoxifen as adjuvant treatment. Tamoxifen, which is an antioestrogen, appears to bind to the intracellular oestrogen receptors thereby rendering the tumour cells less sensitive to the circulating oestrogen [Nicholson et al, 1977]. Controlled clinical trials of tamoxifen administered as adjuvant therapy to women with early breast cancer have convincingly shown that it prolongs the disease free interval and it reduces the rate of mortality in the treatment group [Baum et al, 1985].

MANAGEMENT OF METASTATIC CANCER OF THE BREAST

The most common sites for metastatic spread from cancer of the breast are bone, liver, lung, brain, and skin. It is doubtful whether any patients are "cured" following diagnosis of metastatic breast cancer. However, it seems probable that survival is prolonged by the administration of hormone therapy, endocrine ablation or chemotherapy (or sometimes through a combination of these). Even neurological symptoms caused by brain metastases can be alleviated by the administration of radiotherapy. The prognostic factors of primary advanced local disease were outlined by

Rubens et al [1977]. He studied 184 women with unresectable Stage 3 cancer who were treated with radiotherapy. Survival was poor (median 25 months) and at five years only 13 per cent were alive. When surgery is a possibility with Stage III patients five years survival is much improved [Fracchia et al, 1980].

In metastatic breast disease the type of therapy is a major factor influencing prognosis. However the most important prognostic factors in metastatic breast disease are the disease-free interval and the site(s) of the metastatic disease.

Patients with a very short disease-free interval (i.e. interval between primary therapy and recurrence) have a very poor prognosis [Fracchia et al, 1967; Cutler et al, 1969]. In addition, the site of the metastatic disease and also number of sites are critical as prognostic factors: "visceral" patterns of metastatic disease herald a very poor prognosis (liver, lung, brain, peritoneum and pleura). In addition, patients with multiple sites have even worse prognosis.

In a study by Cutler et al [1975], the median survival for those with one site of metastatic disease was 19 months. However, those with four or more sites of metastases the median survival was six months. The sites of involvement which carry the poorest prognosis are the liver and central nervous system.

Oestrogen receptor status (ER) has been correlated with disease-free interval and survival after primary surgery, tumour histology, tumour cell kinetics and response to hormone therapy [Fisher et al, 1981]. An important conclusion emerging from such studies is that tumours which lack oestrogen receptors are kinetically more aggressive, and those patients who are ER negative have shorter disease free intervals after surgery and poorer survival than those patients who are ER positive. There also appears to be a relationship between the oestrogen receptor status and the site of recurrence: patients who are ER negative tend to have visceral recurrences and those who are ER positive tend to have bony metastases.

Figure 2 :Prognostic Factors in Metastatic Breast Cancer

Performance status
Disease-free interval
Age/menopausal status
Hormone receptor status
Histological grade
Predominant disease site
Number of disease sites
Prior therapy: radiotherapy/chemotherapy/hormone therapy
Labelling index
Clonogenicity

[Williams and Buchanan, 1987, p148]

Medical management of local recurrence is dependent upon whether there is systemic disease and what type of primary therapy has been given. Those patients who have local recurrence with distant metastases and those who have had surgery and irradiation as primary treatment are generally treated with chemotherapy or hormonal therapy, or sometimes a combination of both. Sometimes patients who had surgery followed by radiotherapy may be suitable for further surgery or in the case of local relapse have additional radiotherapy.

Hormonal Therapy in the Management of Metastatic Breast Cancer

Hormonal manipulation via endocrine therapy has become a standard initial approach for patients with advanced disease. The hormone receptor status of patients is crucial in these patients. Those who are oestrogen receptor positive have the best response rate to hormonal therapy. Other good indicators suggesting the patient will respond to hormone therapy are a long tumour-free interval and that they responded previously to endocrine therapy.

Nowadays ablative therapy is seldom used in advanced or metastatic cancer because the range and effectiveness of drugs with hormone blocking activity has increased in recent years. Tamoxifen, which is an antioestrogen, appears to bind to the intracellular oestrogen receptors thereby rendering the tumour cells less sensitive to the circulating oestrogen [Nicholson et al, 1977]. Tamoxifen is the treatment which is commonly used with both pre and post menopausal women. The reason for this preference is that it causes fewer troublesome side effects and not

because it is more effective than other treatments.

Chemotherapy of metastatic breast cancer.

As with other therapies adopted as treatment for patients with metastatic cancer of the breast, cytotoxic chemotherapy does not have a curative effect. However nearly twice as many patients respond to chemotherapy as to hormonal treatment. It has been found that combination chemotherapy such as CMF (cyclophosphamide, methotrexate, and 5 fluorouracil) has a better response rate than use of single agents [Rubens et al, 1992]. However the response rates are similar if the single agent is given in higher and more intensive doses. The optimal duration of chemotherapy is not known. If there is obvious tumour response or the disease has remained static after six weeks of chemotherapy, continuation of treatment is advocated. The combination chemotherapies are most often used in the U.K. Further research studies are being carried out as there is little information on the effect of chemotherapy on long term survival. The side-effects of chemotherapy for the control of metastatic breast cancer include alopecia, nausea and vomiting, dry mouth, and sweating. Concern is often expressed about the value of chemotherapy in palliating breast cancer.

Radiotherapy in Metastatic Breast Cancer

Radiotherapy may be used to palliate the symptoms of metastatic breast cancer. For example, patients with skeletal metastases can of ten have very painful symptoms and this can be markedly relieved by administration of a single dose of radiotherapy. In addition, radiotherapy reduces the risk of pathological fractures where bony metastases are present. Radiotherapy can alleviate the severe symptoms caused by collapse of vertebrae affected by disease, and direct compression of nerves due to tumour growth (e.g. tumours causing brachial plexus lesions). In all these examples cure is not a possibility but palliation is the aim of treatment.

CONCLUSION

This Chapter outlines the epidemiology and treatment of breast cancer. It is clear from this discussion that the treatment of breast cancer adopts a wide range of treatment options: surgery; radiotherapy; chemotherapy; and hormonal therapy. As a direct consequence of this vast range of treatment options, patients may face a wide range of side-effects from their treatment which may cause a wide range of rehabilitation problems.

Chapter Two

REHABILITATION IN CANCER CARE

Introduction

This Chapter outlines the generic definitions of rehabilitation and disability and reviews the literature on rehabilitation in oncology, co-ordination of rehabilitation services and rehabilitation of patients with breast cancer.

DEFINITION OF REHABILITATION

Rehabilitation has been defined as the "restoration of patients to their fullest physical, mental and social capability" [Mair, 1972]. The dynamic process of rehabilitation mirrors the view of the illness as a process which consists of various stages: abilities and goals are continually changing as a direct consequence of illness. A recent survey by Martin [1988] found that one in eight of the population has a disability, therefore the need for rehabilitation is great. Rehabilitation is most successful when it begins early and is preceded by and coexists with effective preventative measures. Prevention of unnecessary loss of function resulting from contractures, pressure sores, nutritional deficits and other problems often shortens the period of rehabilitation and maximises outcome.

Rehabilitation for the patient with cardiac disease, spinal injury, following a stroke, or locomotor problems is recognised as essential, the ultimate goal being the re-establishment of the patient as a functional individual in his or her own environment. Rehabilitation, therefore, generally aims to improve function when a disability has occurred due to illness or injury: "disability" in the context of health experience being defined as any restriction or lack of ability to perform an activity in the manner or within the range considered normal for a human being [Wood, 1975]. Although the rehabilitation team is aware of the specific cause of the disease, their emphasis is on the nature of the changes in function and requirements for improving them rather than on the disease itself. Each individual with a disability needs opportunities for improving and maintaining functional ability, regardless of the cause of their disability.

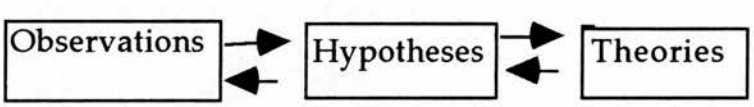
CANCER REHABILITATION

In recent years there has been increasing interest in rehabilitation of the patient with cancer. There is a considerable amount of literature relating to cancer rehabilitation, the overwhelming majority of which come from the United States and have been published during the last fifteen years. This literature falls roughly into two broad categories.

The first category consists of details of how and why rehabilitation of patients with cancer should occur, and contains the majority of the published papers. No data is included in these publications to give weight to any proposed argument, and therefore these are based on arguments from persuasion and rely on anecdotal "evidence" as opposed to recorded data. Not surprisingly therefore, there are a number of questions and doubts which come to mind when critically evaluating these discussions. This category will be referred to as the "prescriptive category".

Only a minority of publications adopt a scientific method which has been represented diagrammatically in a simplified form by Polgar and Thomas [1991] (see Figure 3) and these form the second category: the "scientific category".

Figure 3: The Scientific Method [Polgar and Thomas, 1991, p 11]



PRESCRIPTIVE CATEGORY

Despite the fact that there is a considerable amount of literature subsumed under this category, it lacks structure and a theoretical orientation. Many authors have produced papers of a "philosophical" nature which describe rehabilitation in cancer care or consist of observations derived from a single case. The result of this approach is a body of papers containing diverse beliefs and opinions that cover numerous disciplines and which

necessarily lead to difficulties in making comparisons between them and identifying a unified approach. However in order to evaluate these contributions, they can be looked at according to: (a) method and approaches to cancer rehabilitation; and (b) areas of interest/ concern in cancer rehabilitation.

a) Method and approaches to rehabilitation of the cancer patient

Goal orientated approach

Dietz has written several papers spanning fifteen years in which he adopts a goal orientated approach to rehabilitation of the patient with cancer. Dietz refers to the notion of adaptation:

> "Readaptation, defined as accommodation or adjustment to or adjustment to personal needs for survival and maximum function, is considered the synonym for rehabilitation. Rehabilitation should be provided to enhance the quality of survival, regardless of life expectancy. The objectives are achievement of maximal physical, psychosocial, emotional, and, when possible, vocational rehabilitation of patients and development of training programs for medical and other personnel involved in such rehabilitation." [Dietz, 1985, p 1501]

This approach to rehabilitation as adaptation avoids the popular scepticism towards the application of the term "rehabilitation" to the area of cancer. This appears to many as paradoxical because the traditional view of cancer is one of despair and hopelessness with imminent death whereas "rehabilitation" implies cure.

In addition, this view of rehabilitation of patients with cancer retains the traditional or generic definition of the rehabilitation process which is designed to maximise a patient's physical, mental, social and vocational potential . Hence it would appear that there is a transfer of the traditional model of rehabilitation to the area of oncology. However, despite the widespread instigation of rehabilitation programmes to other medical conditions a:

> "deep seated fear of cancer has, for a long time, prevented widespread public understanding of the potential for cure or long- term survival and rehabilitation."[Dietz, 1980, p 145]

Dietz adopts a goal orientated method of rehabilitation. These goals are preventive (when the disability can be predicted), restorative (when the patient can be expected only to have minimal or residual handicap), supportive (if the patient will have to tolerate ongoing disease or permanent disability), and palliative (if there is advanced disease and basic disability cannot be corrected, but where training can aid performance) [Dietz, 1974].

These goals, Dietz argues, must be "appropriate and obtainable toward which treatment is directed" and " the goal for each patient is determined by an aggregate of factors relevant to the individual" (age, type and stage of neoplastic disease, other concomitant disease, inherent physical ability, social background, basic education and job or work experience) [Dietz, 1985, p1502]. Dietz does give some practical guidelines to apply these concepts by arguing that a rehabilitation programme for each cancer patient should be implemented as soon as possible and not wait until definitive treatment has been completed, by which time disability may not be remediable.

Multidisciplinary Team

Dietz maintains that a multidisciplinary team approach to rehabilitation of the patient with cancer is the best way to provide maximum help. The members of the team include the patient's physician or surgeon, the nurses, therapists and ancillary personnel.

Interestingly this list of members of the rehabilitation team does not include the patient and his/her relatives. Kudsk and Hoffman [1987] argue that the most important members of the team are the patient and his/her family. They must be included and involved with all aspects of the rehabilitation programme including identification of needs, goal setting and determining the treatment and techniques. The inclusion of the patients and his/her family in the rehabilitation team is very much in keeping with the current view that only the patient can properly evaluate his/her quality of life [Slevin, et al., 1988]. Dudas and Carlson [1988] make the same point by making reference to the fact that the desirable aim in rehabilitation of the patient with cancer is that there exist mutual agreement within the multidisciplinary team which must include that

patient and his/her family. This agreement concerns both long and short term goals. In order to achieve the appropriateness of the goals:

> " the involvement of the patient and family in the development of these goals will enable them to verbalize the patterns of activity that are most important for them to maintain or restore.....Otherwise, time may be wasted teaching patients to perform activities that are little significance to them." [Dudas and Carlson, 1988 p 185]

Therefore it would seem an appropriate inclusion of the patient and his/her relatives to the rehabilitation team. This, perhaps, would be one way of achieving "appropriate" rehabilitation goals.

Habeck and colleagues [1984] on the basis of a review of the literature and a single case study offer seven principles of cancer rehabilitation, which embody some of the principles already mentioned.

> "1. Comprehensive care is provided to address the needs of the whole person - each person's life possesses a unique blend of psychological, social, vocational, economic and physical factors.
>
> 2. A team approach is used to achieve co-ordinated interdisciplinary care.
>
> 3. Goals for rehabilitation are derived from the effects of medical problems in accordance with prognostic expectations.
>
> 4. Education is a major component of the rehabilitation process.
>
> 5. Intervention occurs as soon as the likelihood of disability is anticipated.
>
> 6. The unit of care includes both the patient and the family.
>
> 7. Rehabilitation needs must be reassessed on a continuing basis and met throughout all phases of care." [Habeck et al, 1984, pp 317-318]

These principles make common sense and Habeck's reference to a case study makes the points more clear as to how these principles can be transferred into practice.

One criticism which can be levelled at this type of approach however, is that it lacks scientific evaluation. If these principles are to stand as the gold standard for effecting comprehensive rehabilitation of patients with cancer it must be tested against some other method. It is only through this

testing that rehabilitation in cancer care can avoid the anecdotal or idiosyncratic tendencies which have plagued the development of the paramedical "sciences".

b) Areas of interest/ concern in cancer rehabilitation

Barriers to cancer rehabilitation

Cancer is not just one disease; instead it is an "umbrella" term manifesting itself in many varied ways depending on the nature of the neoplasm and the specific site involved. As a result, both the cancer itself and the particular therapy adopted can produce significant and diversified long term and permanent functional restrictions and losses. This can be the case even in instances of "cure" .

Rehabilitation of the patient with cancer can, however, attempt to redress the balance, enabling the limitations imposed by the disease and/or treatment to have a less debilitating effect on overall lifestyle. However, application of rehabilitative principles is dependent on the attitudes of both society and health care workers.

Many papers concerning rehabilitation in cancer care make reference to the effect that the negative or fearful attitudes towards cancer has had on the implementation of rehabilitation programs in this area [Dietz, 1980; McAleer and Kluge, 1978; Dudas and Carlson 1988; Kurtzman et al,1988].

Dudas and Carlson [1988] refer to studies on nurses' attitudes towards cancer patients to support her argument that the attitudes of health care professionals have contributed to the barriers preventing the instigation of comprehensive cancer rehabilitation programs. In particular, she mentions the study by Groszek [1981] where he interviewed 32 randomly selected registered nurses working on acute medical and surgical wards. The findings of the study revealed that the nurses perceived cancer as a terminal disease. In addition when the nurses were presented with various scenarios of patient situations with either cancer or some other chronic illness, the cancer patient was identified by the nurses as terminally ill significantly more often than the patient with other chronic diseases.

Dudas also refers to the study by Solodky [1986] where 28 nurses working on an oncology ward were interviewed. The nurses were asked their perceptions of cancer patients' prognoses compared with patients with coronary heart disease. The findings revealed that the nurses held a more pessimistic view towards the prognosis of patients with cancer compared with patients with coronary heart disease. Dudas points out, therefore, that nurses "still express negative stereotypes and pessimism about patients with cancer despite improved mortality statistics and advancements in early detection and treatment" [Dudas and Carlson, 1988].

Watson [1986] argues that a rehabilitation philosophy provides a means of fostering a positive attitude of nurses toward cancer. She writes that attitudes are closely related to behaviour: a negative attitude manifests itself typically in avoidance, dislike, discomfort etc. whereas positive attitude is reflected in the desire to do the best for the object of the attitude, and to help. Watson refers to the studies detecting nurses' negative attitude toward caring for cancer patients. However, Watson argues that a potential solution and a method of attaining a positive attitude is through the adoption of a rehabilitation approach. The adoption of such an approach, according to Watson, would provide the means by which the nurses altered their perception of the patient with cancer: perceiving them in a more positive light.

Adopting a rehabilitative approach allows the nurse to focus on the disability encountered by the patient with cancer, instead of being preoccupied with the "cancer". The rehabilitative role of the nurse becomes one of reducing the degree to which the disability becomes a permanent entity or interferes with everyday life, irrespective of how long that life may be.

Other barriers to successful implementation to rehabilitation programs which have been mentioned by authors appear to be a direct consequence of the attitudes toward cancer. For example, Dietz [1978] points out that the American Cancer Society estimated that 90 per cent of patients trying to return to work face serious discrimination:

> " Basically, employers and fellow employees fear the cancer patient, particularly if he has an obvious physical handicap, or cosmetic deformity.....some employers fear increasing sickness

> and prolonged sick leave, higher costs for company health and life insurance and other fringe benefits." [Dietz, 1978, p 27]

Such attitudes persist, despite current knowledge of potential for cure and control of the disease. Dietz argues that it is the physician's responsibility to take an active role in attempting to return his/her patient to work. This can be done through educational programs to personnel directors, but also through active participation in the legal and insurance agencies to attempt to change out of date policies.

Allen and colleagues [Allen et al., 1988] noted that despite over 5 million persons being alive in the U.S. with a history of cancer (three million of these considered cured), the state federal rehabilitation closures (case load) for 1980 revealed that persons with cancer and coronary heart disease constituted less than 3 per cent of all case closures.

These findings conform with the results of other research studies (Dietz 1981, Goldberg 1977, Goldberg et al. 1980] which suggest that:

> "Many persons with life threatening disabilities are not receiving the rehabilitation services for which they are eligible under the 1973 Rehabilitation Act.....When considering the financial loss to society as well as the loss of human potential the cost is phenomenal." [Allen et al., 1988, p 62]

Allen and his colleagues continue to elucidate the current barriers to rehabilitation for individuals with life threatening disabilities. The barriers which they examined were: (1) individual's physical condition; (2) state federal agency policy; (3) employer attitudes; (4) the person's psychosocial adjustment to the condition; (5) the competence and training of the rehabilitation professional. According to Allen et al., the person's physical condition can be a potential barrier to successful rehabilitation:

> "This barrier is deceptive because of the confusion between the concept of diagnosis and that of physical condition. While persons with the same diagnosed condition often share similar symptomatology, it is a critical mistake to make broad assumptions based exclusively on diagnosis." [Allen et al., 1988, pp 62-63]

The other barrier which Allen et al. refer to, which has not been covered in this literature review, is the person's own psychosocial adjustment to the disability. This is an important factor in the effective implementation

of rehabilitation, and one which is rarely mentioned in the other articles reviewed. The approach adopted by Allen et al. outlines the effect that advancements in medical treatment have had in increasing functional life expectancy. Allen et al. argued that an individual's psychosocial adjustment to disability has a profound effect on the potential for optimum rehabilitation and quality of life experienced by the individual: "when adjustment is poor, rehabilitation is impeded, if not completely thwarted" [Allen et al., 1988, p 69].

Summary

Many authors have registered their concern for the need of comprehensive rehabilitation programmes for patients with cancer. The papers reviewed above concerning the method and approaches to rehabilitation in cancer care do not rely on a 'scientific' method of approach. Instead they rely upon arguments from persuasion, anecdotal 'evidence', or observations from a single case study. Despite intuitive motivation behind these articles, problems arise in attempting to institute the programmes and methods described because many interpretations can be bestowed on the views expressed. As a result, authors need to be quite strict and give specific details as to the method of how these principles are to be transferred into practice.

However, the papers which surveyed the barriers to comprehensive rehabilitation did use findings from other studies to support their particular argument. Therefore, despite, not using data from the author's own study, they made quite specific reference to 'scientific' studies on e.g. nurses' perceptions of the prognosis of cancer patients etc. The argument that there were potential barriers to rehabilitation seemed to be grounded on 'fact' as opposed to personal opinion.

THE SCIENTIFIC CATEGORY

As mentioned above there are surprisingly few published papers which adopt a scientific method of approach in rehabilitation . However one such study which has been adopted as the paradigm example of quantifying the need for rehabilitation in a population of cancer patients and specifying the reasons for the lack of appropriate referral to an

appropriate member of the rehabilitation team is the study by Lehmann and his colleagues [Lehmann et al., 1978].

This study is the main reference for the assessment of need for rehabilitation services in a population of cancer patients. In addition Lehmann et al. argued that a significant proportion of these patients with functional limitations could be treated effectively once they were referred to the appropriate therapist/ specialist.

Lehmann took a sample of 805 cancer patients and they were screened in order to identify: (1) rehabilitation problems encountered in patients with cancer at different sites; (2) the need for rehabilitation services; (3) gaps in the delivery of rehabilitation care.

A major finding of this study, and regularly quoted in papers advocating the necessity of rehabilitation in continuing cancer care, was that the main barriers to optimal delivery of rehabilitation care were the lack of identification of patients problems and/ or the lack of referral to available services by physicians unfamiliar with the concepts of rehabilitation.

Despite the innovative ideas motivating this study, there are major methodological shortcomings in both the design and analysis of Lehmann's study. Lehmann's description of the methodology is unclear. It would have been helpful, for example, if Lehmann had defined "rehabilitation " and "rehabilitation problems". The assessment tools which he adopted were unstandardised questionnaires therefore it is unclear what was actually measured, and what the reliability and validity of the tests/scales were. In addition, Lehmann omits to mention when these assessments occurred because it would have been extremely helpful for the reader to know if the patients were screened one month after primary therapy or the stage of the cancer.

Harvey and colleagues [Harvey et al., 1982] undertook a study to analyse cancer rehabilitation programs implemented at various facilities throughout the United States in order to identify key methods of approach, team composition, program emphasis, evaluation procedures, and program results. This was achieved by adopting a survey questionnaire designed to gather information about method of organisation, makeup of professional treatment teams, program

emphasis, evaluation methods and results. Further details of these questionnaires were not included.

These questionnaires were sent to 95 centres, and 54 completed questionnaires were returned. However, 18 of these were disqualified because the centre was undertaking a research project of its own or the questionnaire was incorrectly completed. Therefore, data from 36 respondents were analysed.

The findings of this study appear to support the arguments discussed in the earlier section described as the 'prescriptive studies': a multidisciplinary team is implied by comprehensive rehabilitation of the person with cancer; the team members include oncology/ rehabilitation medicine specialist; social worker; psychologist; physical therapists; oncology nurse; occupational therapist. In addition, the service was delivered in goal/ problem orientated manner.

Contained in the scientific category are studies concerning vocational rehabilitation. The long term vocational problems which face a cancer patient can be profound. A person's sense of self-worth and identity are often strongly associated with their work. Therefore when the ability to work is affected due to a diagnosis of cancer the consequences are far more widespread than simply financial.

Many papers concerning rehabilitation of the patient with cancer make reference to the vocational rehabilitation problems encountered. These papers [Mellette, 1985; Kutzman, et al., 1988] make reference to studies concerned specifically with vocational problems encountered by patients with cancer. Extensive investigations have been carried out by Feldman of the Californian branch of the American Cancer Society. One study by Feldman [1976] dealt mainly with the experiences of 92 white collar workers with cancer of the breast, colo-rectal cancer and head and neck cancer. These patients had been diagnosed in 1973 and were followed up in the Cancer Surveillance Program of the University of Southern California. Feldman found that patients frequently felt that they were trapped in their job because they were afraid to change their job and potential risk of losing medical insurance and sick leave entitlement. As a result the cancer patient may be reluctant to seek promotion or a higher paying job because of the possibility of employment discrimination, denial of insurance coverage etc.

Summary of literature on rehabilitation in cancer care

Cancer is a complex disease: it manifests itself in many forms dependent on the particular site involved. In addition, there are many types of treatment which, in themselves, can have dramatic side effects. Studies suggest that the main barriers to optimal rehabilitation of the patient with cancer are the lack of identification of patient problems and/ or the lack of awareness of available rehabilitation services. In addition, the stigma of cancer persists resulting in the lack of acknowledgement what rehabilitation has to offer patients with cancer which can cause long-term vocational and social problems.

The study of the impact of the disease on the patient's rehabilitation status is compounded by many factors:

(1) The type of cancer;

(2) The stage of the cancer;

(3) The treatment of the cancer.

Understanding of these three factors is crucial in the design of any study of patients with cancer. Some of the methodological shortcomings inherent in such studies of monitoring rehabilitation needs are:

1) Many studies "lump together" patients with cancer as a single group [Lehman et al., 1978] As a result of treating cancer patients as a homogeneous group, many factors such as site of the cancer, stage of the cancer, treatment of the cancer are not examined and therefore findings can be superficial or blurred.

The motivation behind a descriptive study of rehabilitation needs would intuitively be to plan therapeutic intervention. If, however, such factors as site of cancer, stage, and treatment are overlooked, little or inadequate information would be provided in order to plan therapeutic intervention.

2) Many studies were conducted on the basis of a single interview with the cancer patient [Ganz et al., 1987]. As a result, a single ' snap shot' view of the rehabilitation problems encountered would have been generated. However, on the basis of such a snap shot view one would not know the

duration of any rehabilitation problems- whether permanent or transitory.

3) Many studies adopt unstandardised questionnaires, the psychometric properties (validity and reliability) of which were not known.

Therefore the recommendations for methodological approach regarding studies into rehabilitation needs of the patient with cancer would be:

1) disease specific

2) stage specific

3) need to identify cancer treatment adopted

4) need to adopt standardised questionnaires

5) need to repeat the interview at regular intervals.

CO-ORDINATION OF REHABILITATION SERVICES

It is clear that many areas of functioning are subsumed under the term "rehabilitation": physical; psychological; sexual; vocational; and social. In order to address these varied needs, rehabilitation is best addressed through the combined efforts of the multidisciplinary team. However, one clear finding of other studies in rehabilitation medicine is the problem of co-ordination of rehabilitation services. McBride stated that:

> "rehabilitation nurses have long been aware that to assist their clients in maximizing their functional capabilities and independence, coordination between health care providers and community resources is essential" [McBride, 1992, p67].

In addition, in oncology, the problem of rehabilitation is complicated further, as highlighted by Lehmann and his colleagues [1978] who found that the main barriers to optimal delivery of rehabilitation care in cancer care were the lack of identification of patients problems and/ or the lack of referral to available services by physicians unfamiliar with the concepts of rehabilitation.

One possible way of resolving the problems of lack of co-ordination of services, lack of identification of patient problems, and lack of referral to available services has been to adopt a "case management approach" or

"rehabilitation co-ordination". This approach has not been adopted formally in the oncological setting, but over the last decade has been adopted primarily in the area of mental health and more recently in rehabilitation medicine. Case management has been defined by five major functions: "assessment; planning; advocacy; linkage; and monitoring" [Chamberlain and Rapp, 1991] and has been used to:

> "coordinate services between organizations, within multiinstitutional organizations, among networks of service providers, and between professionals on interdisciplinary teams" [Nettig et al, 1990, p16].

The case manager has been seen to serve a dual purpose serving as both a facilitator and a gate-keeper. The case manager fulfils a facilitatory role by helping the client make informed-decisions about their care taking into consideration identified needs, abilities and costs. The gate-keeper role of the case manager ensures that the client is receiving the most appropriate, timely, and cost-effective care available from both the perspective of the client and the provider [McBride, 1992]. In addition, the central theme of case management is co-ordination of service provision:

> "the need for case management services is quite evident when it is realised that an individual client may receive services from a bewildering array of facilities and professionals" [McBride, 1992, p69].

A recent study by Davey et al [1992] refers to a "rehabilitation co-ordinator service". This term is perhaps more appropriate in rehabilitation medicine because the meaning of the term is more apparent compared with "case management". Few studies have been carried out, however, to evaluate rehabilitation co-ordinator services.

Summary of rehabilitation co-ordinator services

Despite rehabilitation co-ordination not being formerly used in oncology, the rationale for such a service to patients with cancer is clear: improving detection of rehabilitation problems and referral to appropriate rehabilitation professionals.

REHABILITATION OF PATIENTS WITH BREAST CANCER

Introduction

In recent years there has been increasing interest in the psychosocial sequelae of primary breast cancer and its treatment on women and the literature in this area is vast (this is discussed separately in Chapter Three). In stark contrast, however, few studies focus on the rehabilitation needs of these women. Burdick [1975] argued that "no program concerned with the management of the patient with breast cancer can today be considered complete without including a program for effective rehabilitation". Most authors agree that programs for the rehabilitation of the breast cancer patient should include the physical, functional, vocational and psychosocial needs [Burdick, 1975; Knobf 1985; Wingate et al., 1989].

Functional and Physical Rehabilitation Following Surgery in the Treatment of Primary Breast Cancer

The objective of functional rehabilitation is to "restore normal function to the homolateral hand, arm and shoulder" [Burdick, 1975]. This goal is achieved by careful attention to detail during operation (direction of incisions, wound drainage), immediate post-operative care (elevation of the homolateral arm following mastectomy), post-operative exercises and prevention and treatment of lymphoedema.

Post-operative exercises

Historically indications and timing for post-operative exercise and use of the arm have been at the discretion of the surgeon [Knobf, 1985]. Surprisingly few studies have been carried out monitoring the optimum timing of post-operative exercises.

A prospective investigation was undertaken by Wingate and colleagues [1989] to monitor the progress of patients following a modified radical mastectomy for treatment of breast cancer. The purpose of the study was to demonstrate that post-operative physical therapy was beneficial to to post-

mastectomy patients and that it was not associated with prolonged hospital stay.

The methodology of this study was clearly described. Following biopsy confirmation of breast cancer those patients who were scheduled to have modified radical mastectomy were asked to participate in the study. Following a thorough examination (goniometric measurements of shoulder range of movement, circumferential measurement of the arm), completion of the SCL-90-R [Derogatis 1976] patients were randomly assigned to either: a/ group to receive post-operative physical therapy (n= 61); or b/ group to receive no post-operative physical therapy (n= 54). The assessment was repeated five days post-operatively, and during the post-discharge follow up. Details of the physical therapy treatment given post-operatively to the intervention group were included in the report.

Data were then compared by group using an independent t-test or Chi square test where appropriate. Goniometric measurements revealed that a five days post-operatively a significant difference was found between the treated and untreated goups. Both groups lost range of movement post operatively but the mean shoulder abduction and flexion for the treated group was 129 degrees whereas the untreated group had only 102 degrees shoulder abduction and 105 degrees shoulder flexion ($p<0.001$).

Post-discharge follow up goniometric measurements showed that both groups had improved range of movement, but statistically significant differences were found between the means for shoulder abduction and flexion. On the functional items, the treated group showed significantly better performance on five of the six items than the untreated group. The authors concluded that early physiotherapeutic intervention made a significant contribution to the patient's early resumption of pre-operative functional activities [Wingate et al., 1989].

A more recent paper by Ganz et al. [1987] overcomes many of the methodological problems highlighted above. The authors of this study recognised the importance of specifying the group of cancer patients to be studied because previously most studies had been undertaken on a heterogeneous population of cancer patients and the findings of such studies were difficult to analyse. The aim of the study by Ganz et al. was to provide comprehensive information about the rehabilitation problems of breast cancer patients one month after primary therapy.

The methodology of this study was clear and well documented. A group of 50 cancer patients who had undergone either a modified radical mastectomy (n=31) or a segmental mastectomy (n=19) were interviewed three to five weeks after primary therapy. The sample excluded those with metastatic disease and those who were non-English speakers. The procedure of the interview carried out with the patients was clear. The battery of tests and questionnaires were standardised and the validity and reliability of these had already been ascertained and documented in other publications.

The results were indicated that constitutional and physical problems were the most common problems identified in these newly diagnosed breast cancer patients one month after surgery. These problems consisted of a tight chest wall, difficulty in lifting objects, decreased upper limb mobility, arm weakness, lymphoedema, arm numbness, fatigue, difficulty with household chores, difficulty with physical activities. There was no significant difference between the modified radical mastectomy group and the segmental mastectomy group. Psychological problems formed the next most important category of rehabilitation problems. These included worry about recurrence, anxiety, depression, body image problems and sexual problems related to perceived loss of attractiveness.

Lymphoedema

The incidence of lymphoedema in the arm following treatment for primary breast cancer (surgery and/ or radiotherapy) has been estimated between 7 to 63 per cent [Britton et al., 1962; Farrow 1966]. However, the incidence of lymphoedema has decreased with the advent of less radical surgical interventions and more sophisticated radiotherapy techniques [Adcock, 1990]. However, data on aetiology, aggravating factors, preventive measures and management strategies remain pertinent for those patients who have undergone axillary lymph node dissection. Lymphoedema represents the most frequent long term side effects of surgery.

Prevention is the ultimate goal because once it manifests itself, management of the acute problem is followed by prolonged measures to prevent and control it. Most authors agree of the program for prevention: avoiding trauma and infection, avoiding strenuous lifting, avoiding injections and blood transfusions in the homolateral arm [Burdick, 1975;

Knobf, 1985; Adcock, 1990]. However, there appears to be some debate concerning the management of lymphoedema. The options include intermittent compression therapy (Flowtron) [Gray, 1987], multi-layered compression bandaging [Badger, 1987], manual lymph drainage [Badger and Twycross, 1988], massage, or compression garments. To date, there is a lack of randomised control studies to evaluate the relative efficacy of the various treatment approaches.

Employment and Vocational Rehabilitation Following Diagnosis and Treatment of Breast Cancer

Few studies have been carried out monitoring the vocational rehabilitation needs encountered by women with breast cancer. Given the recent trend for many patients with primary breast cancer to undergo adjuvant chemotherapy and radiotherapy following surgery, patients have to make regular outpatient visits to hospital for many months. It would make sense, therefore, to postulate that patients could incur problems with their employers. Those studies which have monitored the vocational rehabilitation needs have used heterogeneous samples of cancer patients. However, interesting information can be gained from surveying the results obtained from such studies.

Mellette [1985] pointed out that Feldman's study [1978] of blue collar workers revealed that 63 per cent of breast cancer patients were working full-time, 23 per cent working part-time and 64 per cent were working for their pre-cancer employer. In Mellette's own study 63 per cent of the breast cancer patients were working outside the home. Concerning the amount of time lost from work by breast cancer patients, Mellette said:

> "of the 58 women reporting, six missed only 2 weeks or less, and another nine missed three to four weeks. An absence from work of 6 weeks was the most frequent, with 16 women reporting this amount. Half of the fifty women missed from six to eight weeks, and only eight women took off longer periods of time." [Mellete, 1985, p 366]

Mellette noted that Feldman's study of blue collar workers [1978] showed that 59 of the breast cancer respondents had an initial absence from work of nine weeks or more.

Mellette's own study [1985] was a non-randomised survey of 100 women attending a breast cancer workshop, and patients from her own oncology practice. The results gave information concerning the employment problems encountered as a result of receiving adjuvant therapy for treatment of breast cancer. Thirty-eight women out of 98 women had had adjuvant chemotherapy. Of these, 25 were working, but only nine had been off work as a result of the chemotherapy. Six women had been off work two weeks or less, one woman for four weeks, one woman for six weeks, and one for less than a week. Five women out of the 98 had received adjuvant radiotherapy, and of these three missed four weeks off work and the remaining two women did not lose any time off work.

Mellette maintained that women with metastatic breast cancer are more likely to be able to return to work than those patients with metastatic lung disease. In her study, Mellette found that of the 38 patients who had returned to work, 27 patients had active metastatic disease. This contrasted with Mellette's patients with metastatic lung cancer of whom only 13 of 44 continued working full time.

Summary of literature monitoring rehabilitation needs of women with breast cancer

Studies monitoring the rehabilitation needs of women with breast cancer have focused almost exclusively on those women with primary breast cancer. In addition, these studies have focused on the physical rehabilitation needs. The results of these studies suggest that women have a range of physical and psychological problems following surgery for primary breast cancer. The following Chapter surveys the literature relating to the psychosocial implications of a diagnosis and treatment for breast cancer.

Chapter Three

PSYCHOSOCIAL ISSUES RELATED TO BREAST CANCER

Introduction

The monitoring of psychological response to the treatment for breast cancer received scant attention before the 1950's. However, since the 1950's there has been increasing interest in the psychological response to a diagnosis and treatment for breast cancer following the publication of two seminal papers by Bard and Sutherland [1955] and Renneker and Cutler [1952] researching the psychological sequelae of mastectomy. The interest in psychological response to mastectomy grew and was due partly to the debate concerning whether patients should be told their diagnosis. To date, the psychological impact of the diagnosis and treatment of breast cancer is the most widely studied of any cancer. The reasons for this interest are that breast cancer is the most common cancer in women; the breast is intimately associated with sexuality, self esteem and femininity; that the treatment of breast cancer adopts all three cancer treatment modalities (surgery, radiotherapy, and chemotherapy). It could be argued that there is considerable overlap between psychosocial issues and rehabilitation needs. Hence, this Chapter will review the literature relating to the psychosocial sequelae of a diagnosis and treatment for breast cancer.

STUDIES MONITORING THE PSYCHOSOCIAL SEQUELAE OF BREAST CANCER.

Meyerowitz [1980] in an excellent review of the literature relating to the psychosocial sequelae of breast cancer and its treatment described three categories of psychosocial impact: (1) psychological discomfort (anxiety, depression, anger); (2) changes in life patterns (consequent to physical discomfort, marital or sexual dysfunction); (3) fears and concerns (mastectomy and death).

Many studies looking at the psychosocial sequelae of breast cancer and its treatment attempt to measure these domains by the adoption of standardised questionnaires/ measures where details on the reliability and

validity have been established. Indeed, much is owed to the psychologists working in this area for they are mainly responsible for the development of the sophisticated and thorough "tools" of measurement. The development of these measures has meant that studies can be compared with one another and large multicentre clinical trials can be conducted enabling the study of large numbers of patients.

In order to gain some insight into the psychosocial sequelae of breast cancer it is perhaps best to adopt the "process" analogy and look at the various stages of the illness process.

Screening

It has been argued that screening for breast cancer may have adverse psychological effects on the basis that an invitation for screening may make women aware for the first time of their possible susceptibility to breast cancer. In addition, women who are recalled for investigation following the discovery of an abnormality on screening may suffer distress even if further investigations are negative.

Maguire [1982] argued that women who are symptom free and on attendance for screening are diagnosed as having cancer could find it especially difficult to adapt to their diagnosis.

A study by Ellman et al [1989] investigated immediate and persistent psychiatric morbidity in those referred for further investigation because of an abnormal screening result. These results were compared with women attending for screening and with women who were being investigated for breast cancer because of symptoms. The 28 item General Health Questionnaire (GHQ) [Goldberg, 1978] was used to assess psychiatric morbidity in 302 women attending for routine breast cancer screening, 300 women attending for further investigation of a positive screening result and 150 women referred for investigation of breast symptoms. The GHQ-28 was administered to women at clinic and three months later. The results indicated that breast cancer screening does not necessarily lead to any sustained increase in the prevalence of psychiatric morbidity in a community.

This was a thorough research study with good design and method of a sizeable sample adopting a standardised questionnaire whose

psychometric properties were well established. The results supported findings of a previous study by Dean et al [1986] that attendance for screening does not increase psychiatric morbidity. The three month follow up interview demonstrated that there were no lasting increase in anxiety or psychiatric morbidity. This result qualms one of the fears about the screening programme that the anxiety it causes in women with false positive results outweighs the benefit of prolongation of life for some cancer patients [Wright, 1986].

Mastectomy

The literature concerning the psychosocial sequelae of mastectomy for the treatment of breast cancer is vast. This is due in part to the fact that for many years mastectomy was the standard operative procedure for breast cancer. This literature focused mainly on the physical, social and emotional consequences of the loss of one or both breasts.

Despite the varied approaches and designs adopted in these studies, the findings were consistent about women's concerns following mastectomy:

(1) threat of fatal disease;

(2) impact of the loss of the breast on body image;

(3) diminished sense of femininity;

(4) decrease in sexual attractiveness;

(5) fears of recurrence.

Numerous studies [Morris and Royle, 1988; Worden and Weismann, 1977; Maguire et al, 1978] concluded that between 18-25 per cent of women develop an affective disorder within the first year following mastectomy.

Bloom et al [1987] conducted a large prospective study to compare psychosocial functioning in four groups of women. The groups were:

(1) Women who had mastectomy for Stage I or II breast cancer (n=145);

(2) Women who had cholecystectomy (n=90);

(3) Women following breast biopsy for benign disease (n=87);

(4) Women who had had no operation in the previous year (n=90).

These patients were healthy controls.

All the women in the study had no history of significant psychiatric or other medical illness. The findings demonstrated that the women who had mastectomy did not experience serious psychiatric sequelae although they did show higher levels of psychological distress related to social and interpersonal relationships. At one year patients with Stage I breast cancer had a "quality of life" equivalent to the unaffected peers. However those patients with Stage 2 disease who received adjuvant chemotherapy experienced greater levels of distress for 12 months.

In this country, Maguire has contributed substantially to this body of knowledge. More recently, Maguire has been concerned with studies looking at how to improve detection of psychiatric problems in breast cancer patients. In one such study [Maguire et al, 1980] a controlled trial was conducted to determine whether counselling by a specialist nurse prevented the psychiatric morbidity associated with mastectomy and breast cancer. Patients were randomised to have either counselling by a specialist nurse (n=75) or the normal care given by the surgical unit (n=77). The findings were interesting in that counselling failed to prevent the occurrence of psychiatric problems. However, the regular monitoring by the specialist nurse enabled the recognition of psychiatric problems and the appropriate referral to a psychiatrist. Consequently, 12 to 18 months later in the "counselled" group levels of psychiatric morbidity were 12 per cent compared with 39 per cent in the "control" group.

Studies comparing psychological sequelae following mastectomy with breast conserving procedures.

As mentioned in an earlier chapter, studies by Veronesi [Veronesi et al, 1981] demonstrated no difference in terms of survival or disease free interval between those patients receiving either mastectomy or wide local excision and radiotherapy. As a direct consequence surgeons thought they could offer less mutilating surgery without compromising survival or disease free interval. In addition, it was commonly thought that because the operation of wide local excision was less mutilating, consequentially the psychological distress would be substantially less in those patients having wide local excision in the treatment of early breast cancer.

Hence, many studies (at least fifteen) have been conducted to compare the psychological morbidity associated with mastectomy and wide local excision for the treatment of early breast cancer.

Fallowfield et al [1986] assessed 101 women with early breast cancer who were randomised to receive either mastectomy (n=53) or breast conservation (n=48). Psychiatric morbidity, sexual functioning and social adjustment were determined post-operatively. Patients were interviewed at home and the battery of tests were a semistructured interview (which was tape recorded), the Present State Examination, the Hospital Anxiety and Depression Scale and the Rotterdam Symptom Checklist.

According to the data yielded on such examination 11 (21 per cent) of the patients with mastectomy had depressive illness and 14 (26 per cent) were anxious. Among the breast conservation group 13 (27 per cent) of the patients had depressive illness and 15 (31 per cent) had an anxiety state. These figures mean that overall an anxiety state or depressive illness or both was evident in 17(33 per cent) of the patients with mastectomy and 18 (38 per cent) of those treated by lumpectomy.

These figures challenged the common held belief that the mutilating surgery involved in mastectomy was mainly responsible for the psychiatric morbidity found post-operatively. The authors conclude that this "study suggests that the suppositions that: (a) all women with breast cancer wish to retain their breast; and (b) that breast conservation prevents psychiatric morbidity, may well be displaced." [Fallowfield et al, 1986, p1334]. The authors go on to add that "counselling services should be provided for all women treated for breast cancer not just those who undergo mastectomy."

In a more recent study by Fallowfield et al [1990] the objectives were to assess outside a clinical trial the psychological outcome of different treatment policies in women with early breast cancer who had either mastectomy or breast conservation treatment depending on either the surgeon's opinion or the patient's choice. The second objective was to determine the psychiatric morbidity in women undergoing breast conservation was due in part to their participation in a randomised clinical trial.

This was an extremely thorough research study with large sample size

(n=269). Anxiety and depression were assessed using standardise d tools of measurement and were administered at two weeks, three months and one year post-operatively.

The incidence of anxiety and depression and sexual dysfunction were high in all treatment groups. There were no significant differences in the incidences of anxiety and depression between women who underwent mastectomy or breast conservation. Interestingly, there was a significant effect of surgeon type on the incidence of depression observed: patients treated by surgeons who offered a choice showed less depression that those treated by other surgeons.

The authors conclude that there

> "is still no evidence that women with early breast cancer who undergo breast conservation surgery have less psychiatric morbidity after treatment that those who undergo mastectomy"[Fallowfield et al, 1990, p 580].

Hall and Fallowfield [1989] in a thorough review of these studies looking at psychological outcome found that when psychological morbidity was thoroughly investigated in the two groups (mastectomy and breast conservation) using standardised and validated measures in a sizeable sample of women, there was no significant difference in the number of women who were anxious and/or depressed in the two groups. The conclusion of this review was that a significant minority of women with early stage breast cancer (approximately 35 per cent) develop moderate to severe anxiety and/or depression following treatment irrespective of what surgical treatment was adopted. Hall and Fallowfield found that in those studies which included details on body image, patients who had breast conservation had fewer problems related to body image.

One of the disadvantages of the wide local excision technique and radiation is the demand in terms of time: many patients will have had the operative procedure and then, once the scar has healed, have to attend the radiotherapy department as an outpatient on a daily basis for four to five weeks. In addition, some women may also have to return to hospital on an in-patient basis in order to have an irridium implant inserted. This technique has already been mentioned in a previous chapter. However, it should be noted that the patient has to put up with the physical discomfort of the implant, the psychological distress that that may cause

and the further psychological distress caused by isolation because each patient who has the implant can have only "limited access" because of the risk of irradiation to medical staff and friends. In addition, the reassurances of medical staff that these implants are given in order to "clear up any remaining cancer cells" may not act as reassurance, but instead fuel fears that the patient may have that the disease has not been totally removed/ treated.

The picture of psychological distress may be further complicated when the patient is pre-menopausal. There is a policy in some cancer centres to treat pre-menopausal women with adjuvant chemotherapy following breast conservation treatment and radiotherapy. Therefore these women face an even greater treatment time because often these courses of chemotherapy can take up to six months to complete .

These facts can perhaps demonstrate the demands in terms of psychological coping in patients who have breast conservation treatment in early breast cancer and therefore can attempt to explain their apparently high levels of psychological morbidity.

Some researchers have maintained that the counterintuitive findings of equal levels of morbidity in both the mastectomy patients and conservation patients result from the fact that the data is contaminated by patients not being randomised to either treatment: some patients had chosen to have either a mastectomy or breast conservation. The hypothesis underlying this challenge was that if women were allowed to choose their operation they would not suffer psychological distress.

Choice of surgery: psychosocial sequelae

There has been considerable debate concerning the issue of choice of surgical procedure and levels of anxiety and/or depression. The rationale underlying this debate is that if women were allowed to play an active role in the decision-making process concerning the operative procedure for treatment for early breast cancer, they would demonstrate lower levels of distress (anxiety and/or depression) post-operatively. Hence, many studies have been conducted in order to determine the accuracy of this assumption.

Morris and Royle [1988] studied prospectively 30 patients with early breast

cancer to assess whether being offered a choice of surgery (simple mastectomy or wide local excision and radiotherapy) influenced the levels of anxiety and depression pre and post-operatively. The 30 patients were split into two groups who were matched for stage of disease and age: those offered a choice of surgery and those offered no choice. The latter group arose from the fact that they had centrally located tumours and the policy at the study hospital was at that time to perform mastectomy on such patients.

The first group, where a choice was given consisted of 20 patients. Seven patients chose mastectomy and 13 chose wide local excision and radiotherapy. The second group consisted of ten patients who underwent mastectomy. Two groups of patients acted as controls: 31 patients with benign breast disease who did not have surgery; 20 patients who had surgery for varicose veins or gall stones.

Levels of depression and anxiety were assessed using the Hospital Anxiety and Depression Scale (HAD), self esteem was measured using the Rosenberg Scale and symptoms were assessed using the Rotterdam Symptom Checklist. A semi-structured interview was also carried out to monitor the effect of breast cancer on social and work activities and marital relationships.

However only data from the HAD was analysed in this study. Husbands were also given the questionnaires to complete. Patients were seen one day before surgery and thereafter at 2-3 month intervals for a total of 10-12 months. The results demonstrated that there was a marked difference in psychological adjustment between those patients offered a choice of surgery and those not given any choice. Those patients (and husbands) offered a choice suffered less anxiety and depression than those not offered a choice. The authors suggest that:

> "offering a choice of surgery does not appear to be doing any harm to patients and may in fact be reducing the levels of anxiety and depression commonly observed in breast cancer patients" [Morris and Royle, 1988, p 585].

The obvious criticism which can be levelled at this study is the size of the sample (30 patients: 20 patients offered a choice and 10 patients offered no choice). In addition the phrase "offering patients a choice of surgery " requires considerable qualification: how exactly were patients offered a

choice? How was this manoeuvre standardised in order to avoid bias etc. Extreme care has to be used in such studies addressing the issues of decision-making and autonomy. However it remains that this study lends some weight to the argument that choice of surgery reduces levels of anxiety and depression .

However, a study by Levy et al [1989] arrived at a completely different conclusion: when patients were offered a choice, patients were psychologically worse-off compared with patients not given a choice. All women in the study had Stage I or Stage II breast cancer. Two groups of patients were interviewed in this study: 93 patients who were randomised to excisional biopsy (wide local excision) and radiotherapy or mastectomy; 98 patients, 70 per cent of whom elected to have breast conservation therapy (wide local excision and radiotherapy). All patients were interviewed three to five days post-operatively and 3 months later using a well validated mood measure, the Profile of Mood State, Karnofsky ratings were carried out by independent observers on all patients. The two groups were identical at the three month follow-up interview using the Karnofsky rating. However, those patients in the first group who were randomised to treatment i.e. not given any choice, demonstrated decreased levels of distress over time irrespective of treatment (mastectomy or wide local excision and radiotherapy). The second group where choice was offered and 70 per cent opted to have wide local excision and radiotherapy demonstrated significantly higher levels of distress over time and were generally more depressed.

The design of this study was well thought out with good sample size, all patients had similar stage of breast cancer, the researchers adopted standardised tools of measurement and interviewed the patients on two occasions. The statistical analysis was sophisticated. The researchers concluded that "the assumption that a woman is psychologically better off opting for breast conservation may need to be re-examined" [Levy et al , 1989].

An interesting development of this study would be to interview these women over a five year interval to measure mood state. The findings would be particularly interesting in those women whose breast cancer recurred and test out the hypothesis that women who chose wide local excision and radiation suffered higher levels of distress compared with

women who had no choice regarding surgery.

Psychosocial sequelae related to chemotherapy

It is well known that chemotherapy can cause significant side effects. The most common side effects are nausea and vomiting but also include alopecia, fatigue, anorexia, peripheral neuropathies, diarrhoea and sexual problems [Penman et al, 1984]. The side effects vary widely depending on the type of chemotherapy (whether single agent or combination), the dose given, the number of cycles of treatment and whether chemotherapy is given in combination with radiotherapy.

Chemotherapy for breast cancer is usually given in combination form - cyclophosphamide, methotrexate, and fluorouracil with or without prednisone (CMF/P) or cyclophosphamide, doxorubicin with or without fluorouracil (AC/CAF).

An early study by Maguire et al [1980] cast doubt on claims that "adjuvant chemotherapy causes little toxicity and psychiatric morbidity in patients with breast cancer." Comparisons were made to find out the psychiatric morbidity in women having CMF (n=26), melphalan alone (n=15), and no chemotherapy following mastectomy (n=18) using the Present State Examination shortly after surgery and three months and 12 to 18 months later. In addition, the interviewers used a four point scale to rate any physical toxicity. Though the sample was small, the findings seemed to confirm a high level of psychiatric morbidity in patients given CMF and suggested that it w as linked to physical toxicity.

Meyerowitz and colleagues [1983] interviewed 35 women who had received CMF chemotherapy after surgery for Stage II breast cancer 21 months after treatment. All patients had earlier completed a similar interview when undergoing chemotherapy and the results could therefore be compared. This comparison indicated significant improvement in levels of psychosocial functioning in 4 or 5 "life areas" (marital/family relationships, sexual relationships (behavioural ratings), sexual relationships (emotional ratings), financial situation, general activity level, work related activity level). However patients did report continuing disruption in their level of general activity. 44 per cent of patients reported long term disruption in at least one "life area" and 56 per

cent described continuing physical problems related to chemotherapy. Despite these problems, however, 89 per cent said they would recommend a close friend that she hypothetically have the treatment if found to have breast cancer.

Love et al [1989] monitored side effects of chemotherapy, patient distress and patient-practitioner communication in 238 patients having chemotherapy for breast cancer (n=167) or malignant lymphoma (n=71). Patients were interviewed at five points during their first six cycles of chemotherapy using semistructured interviews; a subscale of these patients kept brief symptom diaries. 80 per cent of patients experienced nausea, alopecia, and tiredness. By the sixth cycle, 46 per cent of patients had thoughts of giving up chemotherapy. Ratings of objective difficulty with treatment increased over time. This difficulty could be predicted by the experience of side effects, type of chemotherapy. The number of side effects was the best predictor of objective difficulty with treatment. In contrast, emotional distress was less sensitive to the directly assessable characteristics of treatment. Doctor-patient communication was found to be in adequate in a number of respects.

The psychosocial sequelae of reconstruction

An increasing number of women will choose or are offered breast reconstruction following mastectomy. However, it is estimated that in percentage terms fewer than 10 per cent of women undergoing mastectomy have reconstruction.

Schain et al [1984] argued that there are five main areas of psychosocial issues in breast reconstruction: informational; economic; medical; intrapsychic or self determined needs; and interpersonal or other-determined needs.

Women's response to reconstruction following mastectomy was studied at Memorial Sloan Kettering Hospital [Jacobs et al, 1983] in a collaborative study by psychiatrists and plastic surgeons. 150 women seeking reconstruction were assessed in terms of psychological state and surgical opinion as to the suitability for reconstruction. 117 were offered reconstruction and 83 women were assessed post-operatively. At pre-operative assessment the women were generally well informed and the

reason most often cited for opting for reconstruction was "to feel whole again" and to be rid of the prosthesis. Post-surgical interviews demonstrated that 83 per cent of women were happy (or delighted) with the result. The net effect of surgery was to increase both observed and stated levels of psychological, social and sexual functioning. Indeed the development of more successful and sophisticated implantation techniques may play an important part in rehabilitation the patient following mastectomy.

Dean et al [1983] compared patients who were randomised to have either mastectomy and immediate reconstruction or mastectomy alone. Patients were interviewed using the General Health Questionnaire (GHQ) three months post-surgery and significantly fewer (7 per cent) of the breast implant group had signs of psychiatric morbidity than those women without an implant of whom 36 per cent were experiencing psychiatric problems. However, sexual dysfunction was apparent in both groups.

The Psychosocial Sequleae of Recurrent and Metastatic Disease

It would seem likely that the psychological impact of diagnosis of recurrent disease would be immense given the hopes and expectations invested in the initial treatment. Many years may have elapsed since the initial diagnosis and this may have enabled the women to become hopeful that the disease had been cured and would not return.

Compared with the number of studies looking at the psychosocial sequelae of a diagnosis and treatment of early breast cancer, there is surprisingly little research monitoring the psychosocial sequelae of recurrent or metastatic breast disease.

Despite, for example, some researchers stating that recurrence causes even more emotional distress than initial diagnosis [Holland, 1977], there have been few studies which systematically test this theory. Of the few studies which have been undertaken on patients with advanced disease most have been carried out with "mixed" cancer patients [Plumb and Holland, 1977; Plumb and Holland, 1981]. These studies demonstrated that 20-23 per cent of patients with advanced cancer (at various sites) reported depression. Hopwood [1984] studied the psychiatric morbidity in 26 patients with metastatic breast cancer. She interviewed patients before and

2-3 months after chemotherapy. The results demonstrated that 35 per cent of women were anxious or depressed. In addition the majority of these women responded well to anxiolytic or antidepressant therapy.

Conclusion

It is clear from the previous discussions that the psychosocial consequences of a diagnosis and treatment for breast cancer can be profound. There has been considerable interest in this area over recent years. However, most studies focus on the psychosocial sequelae of primary breast cancer and its treatment paying scant attention to later stages of the disease.

Chapter Four

MEASURES OF REHABILITATION STATUS IN ONCOLOGY

Introduction

Measurement in rehabilitation is beset with difficulties. The definition of rehabilitation as "the restoration of patients to their fullest physical, psychological and social capability" [Mair, 1972] highlights that it is a broadly based topic which spans the activities of many professionals and the multiple needs of patients. Nichols [1979] has argued that rehabilitation owes its scientific development to a number of arts and sciences including sociology, psychology, vocational education and medicine. Due to this diverse background it has been estimated [Bolton, 1985] that there are over 10,000 different tests available to the rehabilitationist. Hence, selection of the most appropriate measurement tool in rehabilitation can be a difficult task.

In addition, in the context of oncology there are important issues to consider in relation to the selection of measurement tools. Fortunately, in the last decade there has been increasing interest in the impact of cancer and its treatment on the quality of life because the benefit of surgery, radiotherapy and chemotherapy on quantity of life is sometimes marginal. The lessons learnt from this area of research can be usefully applied to the present study.

This Chapter is divided into three main sections: a brief review of the required properties of measurement instruments; a discussion of measurement of rehabilitation needs in cancer care; and finally a discussion of the recommendations of the psychosocial oncologists who have been attempting to measure quality of life. Particular measurement tools will also be discussed in detail in the latter two sections.

THE SCIENCE OF MEASUREMENT

In the laboratory disciplines, the term "measurement" implies precision; development of appropriate instrumentation helps this process of measurement. In the natural sciences, subjective judgement plays a minor role in the measurement process. In contrast, however,

measurement in the social sciences seems to rely heavily on subjective judgement. In order to place the therapeutic efforts of medical disciplines such as physiotherapy, occupational therapy, oncology, rheumatology etc. on a sound scientific basis, methods have been devised to measure the more subjective states of human experience and achieve a level of precision. Certain criteria are crucial in choosing a measurement instrument in the form of a questionnaire or scale.

Sensitivity

In choosing a measurement tool it is important that it is able to discriminate or detect all cases of the relevant variable. This is sensitivity which is usually expressed as a percentage.

Validity

When selecting a measurement instrument such as a questionnaire or scale it should possess face and content validity. Face validity is the simplest form of validity in that the instrument appears to be assessing the desired qualities. Content validity is closely related and it is the extent to which the instrument adequately probes the various aspects of the area it is supposed to measure. These two forms of validity consist of a judgement by experts whether the measure appears appropriate for the intended purpose. This type of validity has been called "validity by assumption" [Guilford, 1956] and therefore face and content validity should be regarded as a minimum prerequisite of a measure.

More robust types of validity which require more than simple "peer judgement" can be subsumed under the heading "empirical validity" : empirical evidence which demonstrates that the measure is actually measuring what it is supposed to: concurrent and construct validity. This empirical evidence can be obtained by comparing the results of the "new" measure with an independent external criterion or "gold standard" and the concurrent validity of the "new" measure is usually expressed in terms of a correlation coefficient. When no "gold standard" exists with which to compare the new measure, the construct validity of a measure can be ascertained by assessing the extent to which a measure fits into theoretical constructs which in turn link with other observable measurements. A particular theory should state predictions about

relationships between constructs. If accumulated evidence about a test supports the predicted direction of these relationships then the test is shown to have construct validity.

Reliability

A measure which is valid may not necessarily yield consistent results. Hence a measure must also yield reproducible results i.e. the measure must also be reliable. Reliability is defined as the degree to which two separate, independent measurements of the same thing agree with one another and is usually expressed by a co-efficient of correlation representing the relationship between the two sets of measurements. Like validity, there are different forms of reliability testing. The different forms can be subsumed under two main headings: stability; and internal consistency.

There are a variety of ways of ascertaining the stability of a measure. For example: inter-rater reliability is the extent to which administration of the same test by two or more people yields the same results; intra-rater reliability is the agreement between observations made by the same rater on two different occasions; and test-retest reliability is the agreement of observations on the patient on two occasions separated by some interval of time.

Measures of internal consistency are based on a single administration of a measure. For example, a particular questionnaire may contain several items which address the same underlying dimension. It would be reasonable to assume, therefore, that the responses to each item would be correlated with the scores on all other items. There are a number of ways in ascertaining internal consistency: split half consistency, odd-even consistency. Internal consistency is infrequently tested compared with the stability of the measure over time and between raters.

Summary

It is clear from the discussion above that whatever measures are adopted in a scientific research study looking at the rehabilitation needs of patients with metastatic breast cancer they should possess respectable levels of sensitivity, validity and reliability. The following discussion looks at a variety of measures which have been adopted in this area of research.

REHABILITATION MEASURES OF OUTCOME IN ONCOLOGY

It has already been mentioned that measurement of rehabilitation outcome is fraught with difficulties due to the broad definition of rehabilitation. This difficulty is therefore also inherent in measuring rehabilitation needs of patients with metastatic breast cancer. Perhaps this is one reason why there have been so few systematic studies monitoring the impact of cancer on rehabilitation status. Given the definition of rehabilitation in oncology as "the dynamic process directed toward the goal of enabling persons to function at their maximum level of their disease or disability in terms of their physical, mental, emotional, social and economic potential" [Dudas, 1984], it is clear that in the present study, functioning in each of the above domains has to be measured.

To the author's knowledge, following a detailed search of the literature, the only scale which specifically purports to measure the rehabilitation status of patients with cancer is the Cancer Rehabilitation Evaluation System (CARES) [Schag and Heinrich, 1988].

The Cancer Rehabilitation Evaluation System (CARES) was developed from the Cancer Inventory of Problem Situations (CIPS). The CARES is a self-admininstered questionnaire which assesses the everyday problems and rehabilitation needs of patients with cancer.

The theoretical basis for the development of this questionnaire is a competency based model of coping which was first described by Goldfried and D'Zurilla [1969] and applied to first year college students. It was later used as a model of coping with chronic illness [Turk, 1979; Turk et al, 1980]. According to this conceptual model, coping is seen in operational terms: coping is defined as competent responses to problematic situations. The model has three components: problem specification; response enumeration; and response evaluation. The first component identifies the range of problems which a patient has to cope with and provides a normative database. The CARES attempts to provide a method of data collection, thereby giving a comprehensive database of the problems with which cancer patients must cope. Therefore the CARES is attempting to address the first component of this theoretical model of coping: problem specification. It was the authors' intent with this questionnaire to address more specific components of behaviour affected by cancer and its treatment and not to concentrate solely on the emotional distress.

Patients are asked to rate each problem statement on a five point scale, zero representing "not at all" (no problem) and four representing "very much" (severe problem). The patient is given the written instructions:

> "Below is a list of Problem Statements that describe situations and experiences of individuals who have or have had cancer. Read each statement and circle the number that best describes HOW MUCH EACH STATEMENT APPLIES TO YOU during the PAST MONTH, INCLUDING TODAY. Some sections will not apply to you. Please skip these sections and proceed to the next one as directed."

The CARES can be scored into a Global Score, and five summary subscales (physical, medical interaction, psychosocial, sexual, and marital). The Global Score takes into consideration the varying number of possible problems for each patient. The five summary subscales summarise the major areas of function and at a clinical level they provide a general summary of a patient's status in a particular area.

Two major reliability studies of the CARES have been conducted [Schag et al 1983, Schag et al 1988]. In the first study, 71 patients completed the first version of the CARES twice at a one week interval. CARES was found to have excellent test-retest reliability (mean for reliability coefficients, r= +0.89). In the second study, using the revised version of the CARES, 120 patients completed the questionnaire and then ten days later. Once again all correlations were strong and positive with all the Pearson product-moment correlations being high (r=+0.82). The authors argue that the "instrument appears to have a high degree of reliability and this reliability is consistent across time, patients and other changes" [Schag et al, 1983].

Validity issues have been addressed with the CARES. Because the CARES represents an instrument which is made up of a variety of constructs all of which relate to the range of problems encountered by patients with cancer, validation is a difficult process as there are few other instruments which address such a range of problems (concurrent validity is assessed by comparing the results of the measure with another measure which is seen as the "gold standard" with good reliability and validity). In the first study [Schag et al 1983] CARES (then referred to as the Cancer Inventory of Problem Situations-CIPS) was compared with the SCL-90-R [Derogatis 1977] in order to establish concurrent validity. The SCL-90-R is a measure of psychological distress and has been frequently used with cancer

patients. The authors hypothesised that if the CARES assessed the impact of cancer on daily life accurately, then the overall number of problems would be positively correlated with the results of the SCL-90-R. A high correlation was established by a Pearson product-moment correlation (r=+0.69) which indicated that the relationship between the number of problems endorsed by patients on the CARES and the results of the SCL-90-R was positive and strong.

A second study [Schag and Heinrich, 1988] looking at the concurrent validity of the CARES was carried out with 120 patients with cancer. This was a much more sophisticated study as the CARES was compared with the SCL-90 (to give information about the concurrent validity of the psychological items in the CARES), the Dyadic Adjustment Scale (DAS-to measure the concurrent validity of the items concerned with marital and sexual functioning), the Karnofsky Performance Status Score (to measure the concurrent validity of the physical functioning items in the CARES), and a quality of life visual analogue scale (to measure the concurrent validity of quality of life items in the CARES). The correlations for the validity measures and the CARES' scales were in the appropriate directions. The correlation between the CARES Global Score and the other five summary subscales and the SCL-90 was positive and strong. The Karnofsky Performance Status Score was negatively related to the CARES which is what one would intuitively expect because as the severity of problems increased on the CARES, the Karnofsky Performance Status Score would decrease. Interestingly, the correlation between the DAS and the CARES was not so strong, particularly the relationship between the DAS and the Sexual subscale on the CARES. The authors argued that this lack of strong correlation was due partly to the fact that the DAS has only two questions which relate to sexuality, whereas the CARES sexual subscale has eight questions addressing interest, sexual performance, and sexual dysfunction.

The CARES is available in two forms - as a questionnaire consisting of 139 items; and as a short form (SF) consisting of 59 items. The CARES - SF was primarily developed for use in research studies to assess problem areas and rehabilitation needs. All items contained on the short form are included in the original CARES. The items for inclusion in the short form were selected using data which had been collected from the long form. The CARES - SF rating system is the same as the original 139- item

CARES. Scoring the CARES - SF is similar to the CARES: there is one single score the Global CARES - SF, and there are five higher order factors representing: physical (the physical changes and disruption of daily activity caused by the disease or treatment); psychosocial (psychosocial issues, communication and relationship problems); medical interaction (problems interacting and communicating with members of the medical team); marital (problems associated with a significant marital type relationship); and sexual (problems related to interest and performance of sexual activity).

The psychometric properties of the CARES - SF have been evaluated [Schag et al, 1991]. The data from four samples of cancer patients demonstrated that the CARES - SF is highly related to the CARES (r= 0.98), had excellent test-re-test reliability (86 per cent agreement), concurrent reliability with related measures and acceptable internal consistency of summary scales (alpha= +0.85 to +0.61). In additional longitudinal evaluation of a newly diagnosed sample of breast cancer patients (n=109) who were interviewed at three points in time (one month, 7 months and 13 months after diagnosis) suggested that the CARES - SF is responsive to change over time and is highly related to the Functional Living Index-Cancer [Schipper et al, 1984). Research of the CARES-SF have demonstrated that it possesses the same high levels of validity and reliability [Schag and Heinrich, 1988]. The CARES - SF has been found to be highly acceptable to patients and takes about ten minutes to complete.

The CARES-SF was selected for use in this study because it was thought that the longer version would take too long to complete especially since it was to be used in conjunction with other measures. Possible respondent fatigue in the selected patient group was a risk because all patients had metastatic disease and the likelihood of patients having problems with concentration and lethargy.

Another measure which is specifically designed to measure rehabilitation status is the Edinburgh Rehabilitation Status Scale (ERSS)[Affleck et al, 1988]. Although this was not specifically designed for use with cancer patients, it was thought to be appropriate for use in the present study.

The ERSS measures four dimensions in which changes may occur in the course of a disabling illness. This scale therefore gives a profile of measures in each domain but an overall score can also be given indicating

the overall level of performance of individuals.

The ERSS subscales:

1. Dependence/ independence: The subscale describes the frequency of the patients' acceptance of support and the extent to which he/ she depends on others for self care, economic arrangements and administration of any medicine or treatment.

2. Activity/ inactivity: This subscale measures the patient's ability to perform the physical and intellectual processes involved in occupations, home life and leisure. There is no emphasis on paid employment.

3. Social integration/ isolation: This is a social behavioural subscale to monitor the involvement with others. The extent and quality of domestic or social participation is rated.

4. Effect of symptoms on lifestyle: This subscale grades the frequency and severity of any symptoms/signs and the difficulties and distress that arise.

This scale is completed by a researcher or clinician and the patient is rated on each subscale from zero to seven: the higher numbers indicating greater severity.

Studies of the ERSS have been carried out to determine its reliability and validity. It was shown that the ERSS is sensitive to change over time and that it can be used as a simple assessment on the effectiveness of a rehabilitation programme.

Correlations of the ERSS total scores with the total scores Barthel Index [Mahoney and Barthel, 1965] and PULSES [Gresham and Labi, 1984] have also been carried out producing a high degree of correlation between all three scales. More recently, a larger study was conducted [Mattison et al, 1991] in a total of 364 patients attending day centres for the physically disabled. Scores were obtained for the ERSS and the Barthel Index, and in 100 patients additional scores were obtained on the PULSES profile. Correlation of total scores for all three scales confirmed that all three succeeded in measuring disability and all three were significantly related.

QUALITY OF LIFE ISSUES IN CANCER CARE

The explosion of cancer therapy over the past fifty years has brought intense hopes and expectations concerning a "cure for cancer". However, despite many advances in various treatments of cancer, the goal of cure has not been achieved. As a direct consequence of the difficulty in achieving this goal, there has been increasing attention on quality of outcome with the recognition that quality of life is an important issue in cancer treatment research. The addition of quality of life endpoints to the traditional endpoints of overall survival, disease-free survival and tumour response theoretically enables medical researchers to make more informed decisions about risk-benefit trade-offs in the treatment of particular cancers.

However, with the need to collect data on both profiles of quantity and quality of life in patients with cancer, several problems have been encountered. Quantity of life i.e. duration of survival, is relatively easy to measure. However measurement of quality of life is much more complex and basic issues related to its definition have caused considerable debate. Over the past decade, however, there have been increasing efforts to define and conceptualise quality of life. In cancer care the multidimensional approach is widely adopted and many scales have been designed to measure quality of life. Researchers appear to include the three dimensions of health outlined in the World Health Organisation's definition of health "health is not only the absence of infirmity and disease but also a state of physical, mental and social well-being" [1958]. Hence, these researchers include the physical condition of the patient, the psychological well being and the performance of activities to be important in the measurement in the quality of life. It could be argued that there is an extremely broad overlap between research monitoring quality of life and research monitoring rehabilitation status.

Aaronson et al [1991] stated that:

> "there is now general agreement on two central points. First, health-related quality of life is a multidimensional concept that includes the broad areas of functional status, psychologic and social well-being, health perceptions, and disease and treatment related symptoms.....Second, it is the consensus...that quality of life assessment is essentially subjective, with the target individual being the primary source of information on the quality of his or her life" [p 840].

In terms of operationalising this pragmatic approach to quality of life there have been many developments in the design and the implementation of studies monitoring the quality of life of patients with cancer. A number of self administered questionnaires have been developed which ask patients to quantify their psychosocial health status within a range of areas. These questionnaires share the following features:

(1) The majority have been developed specifically for patients with cancer.

(2) The questionnaires have demonstrated adequate levels of face, content, construct and concurrent validity, and test-re-test reliability.

(3) The questionnaire is designed for repeated use in order that the patient's score can be followed over a period of time to evaluate trends both within patients and between groups.

(4) The questions designed are of general applicability, ease and consistency of interpretation: "sufficiently brief and comprehensible to be of practical use in clinical research settings."[Aaronson et al, 1991].

A development has been made by Slevin et al [1988] in an attempt to measure the subjective nature of quality of life. In a study which he conducted it was clear that doctors and health care professionals could not adequately measure the patient's quality of life when compared with patients' self report of quality of life. Therefore it was suggested by Slevin that if measurement of a patient's quality of life is required, it should be done by the patients themselves and not by the doctors or nurses. As a direct result of this and similar research studies, most of the present questionnaires which measure quality of life are in a self report version.

Following a review of the literature on the measurement of quality of life, two further scales were selected for use in the present study as they were thought highly relevant in a study monitoring rehabilitation needs of patients with metastatic breast cancer: the Rotterdam Symptom Checklist [de Haes et al, 1983]; and the Hospital Anxiety and Depression Scale [Zigmond and Snaith, 1983].

The Rotterdam Symptom Checklist (RSCL)[de Haes et al, 1983] was

developed as a tool to measure the symptoms reported by patients with cancer taking part in clinical research. In a study by Trew and Maguire [1982] the RSCL was used to monitor the levels of the patients' anxiety and depression, reflecting the presence of psychological illness.

The RSCL evolved from analysis of the data from three studies using different checklists. These were:

(1) The Hopkins Symptom Checklist which was administered to 352 psychiatric patients, 147 patients with rheumatoid arthritis and 308 "normal" controls [Luteijn et al, 1979].

(2) A symptom checklist used in a study of 150 patients with breast cancer [Linssen et al, 1979].

(3) A Dutch version of the Symptom Distress Scale developed by McCorkle and Young [1978] which was administered to 49 hospitalised patients with cancer.

As a result of factor loadings, items which were thought to be most relevant according to a group of oncology specialists, and answer-distributions the authors arrived at a selection of items suitable for inclusion in the Rotterdam Symptom Checklist. This yielded a 34 item checklist comprising psychological and physical symptoms.

Patients are asked to rate the level of their symptoms over the last week on a four point rating scale (categories: not at all, a little, somewhat, very much). Eight items were added to cover the patient's functional status. Completion of the RSCL takes about eight minutes.

Details regarding the reliability and validity of the RSCL were originally established by de Haes et al [1983]. It was reported in a paper [de Haes and van Knippenberg, 1987] to have established that the RSCL displayed a level of internal consistency of 0.89 and satisfactory levels of content, concurrent and discriminant validity. A more recent study [de Haes et al, 1990] discusses the use of the RSCL to measure psychological and physical distress experienced by cancer patients. Principal component analyses was undertaken in order to establish the stability of the RSCL in three studies. The results demonstrated that the psychological dimension proved to be stable across different populations (in different cancer populations and "control" groups of patients). The reliability of the psychological distress

dimension of the RSCL was consistently high (Cronbach's alpha 0.88-0.94). The physical dimension of the RSCL demonstrated high levels of reliability (0.71-0.88).

The RSCL has been used in a number of studies monitoring the psychosocial impact of cancer and "quality of life" of patients with cancer [Hopwood, 1984; de Haes and Welvaart, 1985; Fallowfield et al, 1986; Morris and Royle, 1988]. In a paper by Maguire and Selby [1989] the authors conclude that "the current "best-bet" for tapping key dimensions of quality of life is the Rotterdam Symptom Checklist".

The Hospital Anxiety and Depression Scale (HAD) [Zigmond and Snaith, 1983] is a brief self-report rating scale which consists of 14 items: seven concerned with the detection of anxiety and seven concerned with the detection of depression. This measure was designed primarily for use with non-psychiatric medical out-patients to detect mood disorders. The items on the anxiety subscale were chosen by Snaith [1982] from the anxiety items in the Present State Examination [Wing, 1973] and from Snaith's own research. Due to the fact that it was designed for patients with physical disease (particularly the depression subscale) it has the advantage that it omits somatic items like tiredness, insomnia, or loss of appetite which could be both due to mood disturbance and physical illness. The depression subscale emphasises anhedonia. Another important feature is that the concepts of anxiety and depression are separated in this scale: some scales summate the two concepts into a "global" score of anxiety and depression e.g. the Hamilton Depression Rating Scale [Hamilton 1967]. In addition, the HAD is extremely simple and quick to complete, taking only five minutes and has been found to be acceptable to patients.

The HAD is extremely easy to score with each item being rated on a four point scale (0-3) and the raw scores for each sub-scale are summed. In order to determine the patient's "caseness" Zigmond and Snaith give "cut-off" points for both anxiety and depression.

HAD "cut-off" scores for anxiety and depression:

0-7 Non-case

8-10 "Borderline " case

11-21 "Case"

Should a score above 11 persist on either the anxiety or depression score (i.e. "case" levels of anxiety or depression) for a period of one month or longer, the patient should be considered for referral to a psychiatrist or psychologist for treatment.

In a recent paper by Maguire and Selby [1989] which reviews methods adopted in measuring quality of life, the HAD scale is recommended as a useful, reliable and valid tool to measure levels of anxiety and depression in patients with cancer.

Many studies have been conducted to determine the reliability and validity of the HAD scale in a variety of health care settings. Zigmond and Snaith [1983] established the concurrent validity for the sub-scales on the HAD and the independent rating of a psychiatrist as +0.70 for depression and +0.74 for anxiety (both highly statistically significant). The sensitivity and specificity were tested to establish the rate of false positive and false negative results. The number of false positives and false negatives for depression were both 1 per cent, and the number of false positives and false negatives for anxiety were 5 per cent and 1 per cent respectively.

Further evidence for the concurrent validity of the HAD has been reported in psychiatric patients [Bramley et al, 1988]. In a heterogeneous group of patients with physical illness Aylard and colleagues [1987] substantiated that the two sub-scales of the HAD were measuring different aspects of mood disorder as the correlation between the two was only +0.04. Furthermore, there were significant correlations of the sub-scales with those patients known to have definite mood disorder (depression=0.77, anxiety = 0.67) [Aylard et al, 1987].

One hundred patients attending a genito-urinary clinic were assessed using the HAD and completed a semi-structured interview, DSMIII. The sensitivity and specificity was compared between the two measures using the cut-off scores suggested by Zigmond and Snaith. The sensitivity and specificity was optimum with the recommended cut-off points. The

specificity was 94 per cent and 68 per cent for depressive disorders and anxiety disorders respectively. The sensitivity was 82 per cent and 70 per cent for depressive disorders and anxiety disorders respectively [Barczak, 1988].

Ibbotson et al [1989] investigated the validity of the HAD as a screening instrument for the psychological distress of 514 patients with cancer. The HAD was compared with two other self-rating questionnaires, the General Health Questionnaire (GHQ) [Goldberg, 1978] and the Rotterdam Symptom Checklist (RSCL) [de Haes et al, 1983]. The three scales were also compared with the Psychiatric Assessment Schedule (PAS) [Maguire et al, 1978] which is a semi-structured interview and in this study was used as a gold standard. Ibbotson concluded that the HAD performed best overall. Maguire and Selby [1989] on behalf of the Medical Research Council's Cancer Therapy Committee on Quality of Life argued that the HAD is a "useful tool for measuring the psychological dimensions of quality of life in cancer patients".

CONCLUSION

There are many issues to consider in relation to measurement of rehabilitation status in cancer care. The importance of sensitive, valid and reliable measures in this area is crucial. Despite there being few systematic studies monitoring rehabilitation needs of patients with cancer, measures which have been tried and tested in the area of psychosocial oncology and quality of life, could be usefully employed in the present study. This follows in the tradition of development of rehabilitation research generally to learn from other specialties [Nichols, 1979]. The next Chapter describes the aims and hypotheses to be tested in the present study and methodology and procedure.

Chapter Five

THE STUDY: AIMS AND METHODS

Introduction

It has already been highlighted that there are few studies which monitor the psychosocial and rehabilitation needs of patients with metastatic breast cancer. A prospective study measuring the rehabilitation needs of these patients would contribute to this inadequate body of knowledge and, in addition, give a broader rehabilitative perspective on the needs of patients with metastatic breast cancer. The relatively new research interest in rehabilitation of patients with breast cancer can adopt the tried and tested methodology utilised in the studies of the psychosocial sequelae of a diagnosis and treatment for breast cancer and recent quality of life studies: to use standardised tools of measurement; and assessing patients on a regular basis in a prospective study design.

This Chapter is sub-divided into two sections: Section A outlines the aims and hypotheses tested in the main descriptive study and the pilot intervention study; Section B separately outlines the methodology and procedures of both studies.

SECTION A

THE AIMS AND HYPOTHESES OF THE TWO STUDIES

The purpose of this section is to state the aims of the present study and the hypotheses to be tested. The study comprised two components: a descriptive component where patients (n=80) were interviewed every eight weeks at home following diagnosis of metastatic breast cancer; and a pilot intervention component where patients (n=17) were randomised to either an intervention group or the control group. In order to describe the aims and hypotheses, the two components will be discussed separately.

THE DESCRIPTIVE STUDY

This component formed the major part of the research study under discussion.

The aims of the descriptive study

(1) To describe the rehabilitation status of a sample of patients with metastatic breast cancer throughout the course of their disease.

(2) To quantify the rehabilitation needs of a sample of patients with metastatic breast cancer at different stages of their disease.

(3) To identify contributory factors to rehabilitation needs in a sample of patients with metastatic breast cancer.

(4) To assess change in rehabilitation needs in a sample of patients from diagnosis of metastatic breast cancer during the following 16-18 months.

(5) To identify predictive factors in the rehabilitation needs in sample of patients with metastatic breast cancer.

The hypotheses tested in the descriptive study

(1) Patients have rehabilitation needs throughout the course of their metastatic disease.

(2) Rehabilitation needs are not detected in the majority of patients with metastatic breast cancer.

(3) Demographic factors (such as age, marital status, social class) are associated with rehabilitation needs

(4) There is a correlation between physical symptomatology and anxiety and depression in patients

(5) Rehabilitation needs change during the metastatic phase of breast cancer.

(6) There are differences in rehabilitation needs of patients receiving different treatments for their metastatic disease

THE PILOT INTERVENTION STUDY

This component took the form of a small "pilot" intervention study: patients were randomised to either (a) the intervention group where they were assessed by a "rehabilitation co-ordinator" or (b) the control group.

The aims of the pilot intervention study

(1) To test out a method of aiding detection of the rehabilitation needs using a rehabilitation co-ordinator.

(2) To test out a method of aiding referring the patient for intervention strategies using a rehabilitation co-ordinator.

(3) To describe the rehabilitation needs of a small sample of patients with metastatic breast cancer throughout the course of their disease in both the intervention and control group.

(4) To compare the rehabilitation needs of patients in the control group and patients in the intervention group.

(5) To assess change in rehabilitation needs throughout the course of the patients' metastatic breast cancer in both the intervention group and the control group.

The hypotheses tested in the pilot intervention study

(1) Patients have rehabilitation needs throughout the course of their metastatic disease.

(2) A rehabilitation co-ordinator does improve the detection of rehabilitation needs.

(3) A rehabilitation co-ordinator does improve referral for treatment of rehabilitation needs.

(4) Patients perceived the services of a rehabilitation co-ordinator to be of benefit during their metastatic disease.

SECTION B

METHODOLOGY AND PROCEDURE

Introduction

This section describes the methodology and procedures adopted in order to pursue the general objective of describing the rehabilitation needs of patients with metastatic breast cancer.

The study comprised two parts: a prospective descriptive study monitoring the rehabilitation needs of patients with metastatic breast cancer at pre- determined intervals (every eight weeks); and secondly, a small experimental component to test out whether these needs could be resolved thereby reducing the overall needs over time. The methodology and procedures of the two components will be described separately in this section.

THE PROSPECTIVE DESCRIPTIVE STUDY: THE METHOD

Subjects

Patients with metastatic breast cancer form two main groups: those who have been treated formerly for primary breast cancer and later re-present with metastatic disease; and those patients who newly present with metastatic breast cancer. Both "types" of patients were recruited to this study.

All subjects in this study had "staging confirmed" metastatic disease according to the TNM method of staging breast cancer. According to this classification M1 indicates the presence of distant metastases. In addition, because patients are usually only "staged" when they first present at the Longmore Hospital, patients who are subsequently clinically diagnosed and are "re-staged" as having metastatic breast disease were included in the study. Eighty-six patients were approached and, as six patients declined to participate in the study, 80 patients recruited in the descriptive component.

Formal agreement with and approval from the physicians working at the Longmore Hospital with metastatic breast cancer patients was obtained before the research plan was implemented.

Approval from the Ethics Committee was obtained before the research plan was implemented.

Procedure

Patients who were suitable for inclusion in this study were identified by the researcher by two methods:

(1) By reading the staging list produced by the Breast Clinic at Longmore Hospital (each week a list of patients who had been staged a few days previously according to the Tumour Node Metastases (TNM) method of classification was available) and if the patient had been found to have metastatic spread, they were subsequently seen at the Combined Breast Clinic held at the Longmore Hospital;

(2) In addition, the researcher read all the reports and medical notes on patients attending the Combined Breast Clinic in order to ensure that no patients had been omitted for possible inclusion in the study.

When a suitable patient had been identified, the researcher introduced herself to the patient at the Combined Breast Clinic and explained verbally the research study and gave the patient the written information sheet to read (see Appendix). At this juncture, the patient was given the opportunity to decline from participation in the study. However, if the patient showed a willingness to participate, the researcher asked the patient to give their home telephone number. The researcher subsequently telephoned the patient at home and asked them whether they still wished to participate in the study. If the patient was willing, an appointment was made for the researcher to visit the patient at home. On the initial visit, the patient was asked to give written informed consent (one copy of which was retained by the patient) after outlining:

(1) the aim of the study;

(2) that they were free to withdraw from the study if they wished to do so;

(3) how often they were required to be interviewed (every eight weeks);

(4) the location of the interviews (in the patient's own home or if the patient had been admitted to hospital, the interview would occur at the patient's bedside).

Only those patients who gave informed consent following a full discussion with the researcher participated in the study.

Participation involved the patient completing a battery of questionnaires and assessment scales every eight weeks following diagnosis of metastatic disease. This assessment usually occurred in the patient's own home. However, if the patient had been admitted to hospital for treatment, the assessment was conducted at the patient's bedside.

The criteria for excluding people from the study were:

(1) Patients not wishing to take part;

(2) Patients who did not have an Edinburgh Postcode;

(3) Non-English speaking patients;

(4) Patients who in the opinion of the consultant responsible are too ill or too distressed to take part (only four patients were excluded on this ground);

(5) Patients who had any previous history of psychiatric illness (only two patients were excluded on this ground);

(6) Patients who had another disabling illness such as rheumatoid arthritis, heart disease etc. (only four patients were excluded on this ground);

(7) Patients over 75 years of age.

A letter was sent to the patient's General Practitioner outlining the aim of the study informing him/her of the patient's decision to participate.

Measurements

In order to describe the rehabilitation needs of a sample population of patients with metastatic breast cancer, it was essential to be able to identify the problems in each of those domains using a particular measure/scale. This is shown in Figure 4.

Figure 4: Rehabilitation Domains and Relevant Standardised Questionnaire

Physical	Psychological	Social	Sexual	Vocational
CARES	CARES	CARES	CARES	CARES
RSCL	RSCL	RSCL	RSCL	
	HAD			
ERSS	ERSS	ERSS		ERSS
INTERVIEW	INTERVIEW	INTERVIEW		INTERVIEW

(CARES: Cancer Rehabilitation Evaluation System;
RSCL: Rotterdam Symptom Checklist;
HAD: Hospital Anxiety and Depression Scale;
ERSS: Edinburgh Rehabilitation Status Scale;
Interview: interview schedule)

Following the recommendations given by Aaronson [1991] regarding methodological approach for studies monitoring quality of life that "it is today almost universally accepted that the patient is the most appropriate source of information on his or her quality of life", the majority of measures adopted in the present study were in a self-report version (the exceptions being the interview schedule and the Edinburgh Rehabilitation Status Scale [Affleck et al, 1988]). The study was multimodal in that a range of tools were utilised. These comprised:

(a) Interview schedule (researcher completed this)

This was compiled by the researcher to record information concerning age, marital status, employment, time since initial diagnosis, which members of the medical team the patient had seen in the previous month, which problems the patient was experiencing, presence of lymphoedema, whether the patient required any functional aid, which Social Security Benefits the patient received (Mobility Allowance, Attendance Allowance etc). A separate checklist completed by the researcher collated additional information obtained from the patient's medical notes relating to the previous and present medical management, site/s of metastatic spread, the severity of the patient's illness.

(b) The Cancer Rehabilitation Evaluation System - short form for research (CARES) [Schag and Heinrich, 1988]

The Cancer Rehabilitation Evaluation System (CARES) was developed from the Cancer Inventory of Problem Situations (CIPS). The CARES-Short Form for Research is a self-admininstered questionnaire which assesses the everyday problems and rehabilitation needs of patients with cancer. Reliability and validity details have been discussed in the previous chapter. This scale takes approximately ten minutes to complete.

(c)The Rotterdam Symptom Checklist (RSCL) [de Haes et al, 1986]

The Rotterdam Symptom Checklist (RSCL) was developed as a tool to measure the symptoms reported by patients with cancer taking part in clinical research. The 34 item checklist was used in the present study in order to monitor psychological and physical symptoms in addition to performance of daily activities. The RSCL takes approximately ten minutes to complete.

(d) The Hospital Anxiety and Depression Scale (HAD) [Zigmond and Snaith, 1983]

The Hospital Anxiety and Depression Scale (HAD) is a brief self-report rating scale which consists of 14 items: seven concerned with the detection of anxiety and seven concerned with the detection of depression. This scale takes about five minutes to complete.

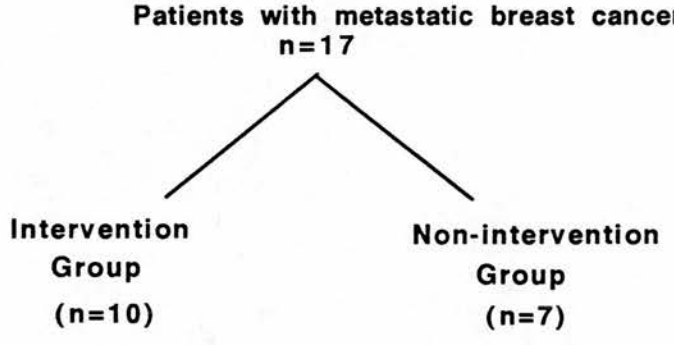
(e) The Edinburgh Rehabilitation Status Scale [Affleck et al, 1988]

The ERSS measures four dimensions in which changes may occur in the course of a disabling illness: independence; activity; social integration; and effects of illness on lifestyle. The ERSS therefore gives a profile of measures in each domain but an overall score can also be given indicating the overall level of performance of individuals. This measure was completed by the researcher.

PILOT INTERVENTION STUDY ADOPTING REHABILITATION CO-ORDINATOR

A separate pilot study was conducted after collection of the data of the initial descriptive phase of this study. This pilot study took the form of an intervention study whereby a small group of patients (17 patients) with "staging confirmed" metastatic breast cancer were randomised to either **(a)** intervention group (n=10) or **(b)** "control" group (n=7). The primary objective of this component was to test out a method of resolving these rehabilitation needs in a pilot intervention study adopting a rehabilitation co-ordinator.

Figure 5: Illustration of randomisation of patients to each group



Subjects

All subjects (n=17) had staging-confirmed metastatic breast cancer according to the TNM method of tumour classification. The criteria for excluding people from the pilot intervention study were:

(1) Patients not wishing to take part;

(2) Patients who did not have an Edinburgh Postcode;

(3) Non-English speaking patients;

(4) Patients who in the opinion of the consultant responsible are too ill or too distressed to take part (only one patient was excluded on this ground);

(5) Patients who had any previous history of psychiatric illness (no patients were excluded on this ground);

(6) Patients who had another disabling illness such as rheumatoid arthritis, heart disease etc. (no patients were excluded on this ground);

(7) Patients over 75 years of age.

Process of Randomisation

Patients were randomised to either the intervention group or the "control" group by the following method: because a maximum of two patients each week were staged as having metastatic breast cancer, patients were randomised as they presented by putting the names of patients on separate pieces of paper in an opaque bag. An independent observer pulled the names out of the bag and were assigned to either the intervention group or the "control" group accordingly.

Measurements

The same measurement tools were used in the pilot intervention study as in the main descriptive study. These were the CAncer Rehabilitation Evaluation System (CARES), the Hospital Anxiety and Depression Scale (HAD), the Rotterdam Symptom Checklist (RSCL), the Edinburgh Rehabilitation Status Scale (ERSS), and a semistructured interview.

Patients in the Control Group

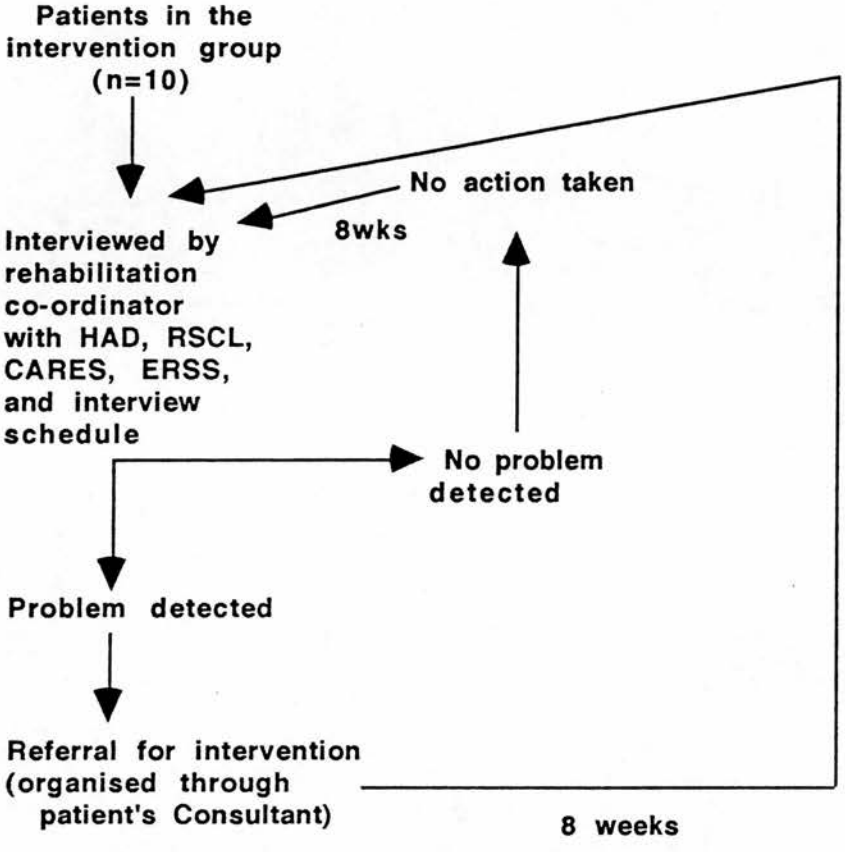
Patients in the "control" group were interviewed every eight weeks at home using the following tools of measurement. The rehabilitation needs were accordingly recorded in order to describe the rehabilitation needs over time.

Figure 6: Flow Diagram to Illustrate the "Management" of Patients in the "Control" Group

Patients in the Intervention Group

Patients in the intervention group were interviewed every eight weeks at home. In the intervention group the researcher acted as a "rehabilitation co-ordinator". A rehabilitation co-ordinator acted as a "case manager" on behalf of the patient and, on the basis of the findings from the assessment tools, the rehabilitation co-ordinator could detect various rehabilitation needs. If and when a problem/need was detected, the rehabilitation co-ordinator referred the patient for appropriate treatment/ intervention (physiotherapist, occupational therapist, social worker, clinical psychologist etc.) through his/her physician, with the patient's consent .

Figure 7: Flow Diagram to Illustrate the "Management" of Patients in the Intervention Group



Therefore as soon as a rehabilitation problem was perceived it was acted on: the rehabilitation co-ordinator referred the patient to the appropriate therapist/ specialist, through the patient's consultant. Whether intervention by a rehabilitation co-ordinator improves rehabilitation status of the patient with metastatic breast cancer was tested out against the "control" group.

A comparison between the two groups using the measures outlined above indicated whether the presence of a rehabilitation co-ordinator effects the rehabilitation status of the intervention group over time.

External Validation

A research assistant interviewed the patients (n=17) on the fifth occasion following recruitment to the study. The purpose of this was to have an objective assessment of patient's rehabilitation needs using the same

measurement tools described above. In addition, the research assistant administered a further questionnaire to ask the patients in the intervention group about their perception of the "rehabilitation co-ordinator service" (whether it was of any value to them, whether the patients felt they had any suggestions if it was offered in the future to other patients etc.) (see Appendix).

Data Handling

All the data from the two studies were entered into a statistical package called Statview on the researcher's personal computer.

Statistical Advice

Advice was obtained from the Medical Statistics Unit, of the University of Edinburgh before the two research studies commenced in order to check the viability of the research method. Subsequent advice was sought by the researcher throughout the course of the study to check data handling and the suitability of various statistical methods/ tests.

Ethical Approval

Before both studies commenced, Ethical Approval was obtained (see Appendix).

Chapter Six

RESULTS

The Main Descriptive Study

Introduction

A consecutive series of 86 patients were approached and, as six patients declined to participate in the study, 80 patients were recruited from the Breast Unit at Longmore Hospital, Edinburgh. These women had metastatic breast cancer confirmed according to the Tumour Node Metastases (TNM) method of staging. Interviews were conducted every eight weeks and data were collected from eight interviews.

Death from disease and effect on sample size

The sample of patients reduced from 80 to 36 during the course of the study. This was due to 44 patients dying from their disease in the 16-18 months following diagnosis of metastatic breast cancer. The tables presented throughout this Chapter give the number of patients completing each interview.

Structure of Chapter Six

This Chapter is sub-divided into four sections: Section A gives details of three vignettes; Section B gives details of the results of the main descriptive study; Section C gives details of the analysis of the data from the patients who survived throughout (n=36) and those patients who died during the course of the study (n=44); Section D gives details of the contribution and association of variables to rehabilitation status of patients with metastatic breast cancer.

SECTION A

VIGNETTES

Before embarking on the analysis of the descriptive component, vignettes of three patients will be presented in order to give some background details of how patient's presented, their treatment, their daily level of function, their concerns and worries, and their scores at each interview. The rationale for this is that it may be difficult to glean from the "raw" scores a picture of patient's rehabilitation status, without prior understanding of the standardised questionnaires.

(1) **Mrs A.** was a 32 year old lady, married with one small child (aged three). Mrs A. did not work because she was looking after her son at home. Before the birth of her son, she had worked as a nurse. Her husband worked full-time as a social-worker. Mrs A. had been diagnosed as having breast cancer three years previously and had surgery, chemotherapy and radiotherapy. Subsequently she was diagnosed as having breast cancer in the remaining breast and had surgery, chemotherapy and radiotherapy. At a subsequent follow-up appointment enlarged supra-clavicular nodes were found and she was admitted for re-staging investigations. She was found to have pleural metastatic disease and was referred to the Combined Breast Clinic and her treatment was planned. She commenced combined chemotherapy: cyclophosphamide, methotrexate and 5-fluorouracil (CMF).

At Interview 1, Mrs A. had not yet commenced chemotherapy and was extremely agitated and distressed. Her mother had died when Mrs A. was a child and she felt certain that she was going to die from her disease just like her mother who had been in great pain and distress at the time of her death. Mrs A. was fully mobile and functionally she was able to carry out all the activities which she had done in the months before the diagnosis of metastases. However, she could not get her mind off her cancer and was not sleeping well, or eating well. Her small son was annoying her intensely as he wanted to play with her and she would shout at him, but then she would feel guilty about it afterwards. She was getting on well with her husband but could not understand why he still loved her.

At Interview 2, Mrs A. continued to be extremely distressed about her disease. She was not coping well with treatment: it did not make her feel sick but she hated the idea of going for chemotherapy and got very agitated before the chemotherapy was administered. She was desperate to know whether the chemotherapy was working and was going to attend a review clinic in two weeks time. Functionally she was able to do all the household chores etc. but continued to be fraught by her young son. She was also having problems talking to her husband about the future.

By Interview 3, Mrs A. had, in the interim eight weeks, been re-admitted to Longmore Hospital for re-staging investigations as she had been complaining of headaches. Metastatic brain disease was diagnosed. Chemotherapy had been stopped and Mrs A. had commenced radiotherapy for the brain metastases. At Interview 3, Mrs A. continued to be extremely anxious. She had lost all her hair and was distressed by this. She could not believe that the disease had progressed so rapidly irrespective of the chemotherapy. Mrs A. had also commenced steroids and they were making her feel hungry all the time and she was concerned about putting on weight. Functionally, Mrs A. was still able to carry out all the household chores but was finding it difficult to communicate with family and friends about the disease.

At Interview 4 there was marked deterioration in Mrs A's condition. She had completed her radiotherapy treatment. Functionally she was able to carry out only light household tasks, was unable to do the weekly shopping, she easily became out of breath and had difficulty climbing stairs. She continued to be very agitated and was extremely worried about her breathing difficulties. At a recent clinic appointment there had been the suggestion that she may re-commence chemotherapy and this worried her greatly because "it did not do any good before, so why should it now".

At Interview 5, Mrs A. continued to be very agitated. Functionally there was not a great deterioration since the previous interview. Mrs A. appreciated that she would not live much longer but this obviously greatly distressed her.

She was concerned how her husband would cope looking after their son after her death. Mrs A. died four weeks after Interview 5 in hospital.

The HAD, CARES global and ERSS scores are shown in Table 1 at each interview.

Table 1

Mrs A's scores on the HAD, CARES and ERSS at each interview

Interview	HAD anxiety	HAD depression	CARES global	ERSS total
1	11	6	1.00	7
2	11	7	1.06	7
3	13	7	1.10	8
4	14	9	1.46	16
5	14	11	1.50	18

It is clear from Table 1 that the HAD anxiety scores were high at each interview. Using the cut-off scores suggested by the authors [Zigmond and Snaith, 1983] Mrs A. scored in the "case" range on anxiety at each interview and in the "case" range on depression at Interview 5. There was also a marked increase in the CARES global score and ERSS total score at Interview 4. The authors of the ERSS [Affleck et al. 1988] suggest that total scores can give an indication of level of functioning and also give a percentage level of dysfunction. Using these, the ERSS total scores of Mrs A can be interpreted to indicate that her level of functioning at Interviews 1-3 was high (25-29 per cent dysfunction). At Interviews 4 her level of functioning was moderate but noticeable (57 per cent dysfunction) and at Interview 5 her level of functioning was low (64 per cent dysfunction).

(2) **Mrs B.** was a 45 year old lady, married with two sons, one of whom was still living at home. Mrs B. worked part-time as a book-binder at the University of Edinburgh. Her husband worked full-time as an engineer with Lothian Regional Council. Mrs B. had found a breast lump on self-examination and had visited her general practitioner, who subsequently referred her to Longmore Hospital. Mrs B. was admitted for staging

investigations. She was staged as T4, N1, M1- and therefore had metastatic disease at first presentation. She was referred to the Combined Breast Clinic and the treatment was planned. She commenced combined chemotherapy: cyclophosphamide, 5-fluorouracil and methotrexate (CMF). The aim of treatment was to reduce the size of the breast tumour and control the metastatic disease. Mrs B. was told that if the breast tumour reduced in size, a course of radiotherapy would be given to the breast lump.

At Interview 1, Mrs B. had just started chemotherapy and had not found many problems coping with it and had not had any noticeable side effects. She was continuing to work part-time and her employers were very supportive and allowing her time off work for clinic appointments and chemotherapy. Her family were very supportive and she was able to carry out the same level of activities as before starting treatment. She said that she was thinking about the cancer quite a lot but that it did not interfere with her work, social life, or relationship with her husband, family and friends.

At Interview 2, Mrs B. had lost all her hair and she appeared distressed and agitated. This had not been noted by the staff at the Western General Hospital, where she was receiving her chemotherapy. She said that she was unable to sleep at night and was finding that she was feeling nauseous as a result of the chemotherapy. She was continuing to work part-time but felt extremely self-conscious about wearing the wig which she said was so obvious. She said that she had lost interest in food and said that she was increasingly irritated with her son. She was not going out with friends as much as she used to but instead was inviting them round to her house for a coffee in the evening. She was feeling quite tired most of the time and this had an effect on her level of function e.g. she could not be bothered to do the housework, but would do still do it because she did not want to look at the layer of dust gathering everywhere.

At Interview 3 Mrs B. was slightly less anxious but had just been referred to see a Clinical Psychologist at the Western General Hospital. She was still being troubled by nausea and said that she got very nervous two days before going to receive chemotherapy because she knew "what the next few days held in store" for her. However, she was pleased that when she

attended the Combined Breast Clinic, the Consultants had noted that her breast tumour had shrunk considerably.

At Interview 4, there was a marked improvement in her mood. She said that the Clinical Psychologist had given her relaxation tapes which she listened to at home. He had also shown her breathing techniques to help her relax. She said the main help had come by being able to talk to someone on a regular basis about how she was feeling and what her worries were. She said that she could not be this "open" with members of the family or with friends. She was still continuing to work but was feeling very tired in the evening, so she was not able to see friends as much during the week but was managing to see them at the weekend. She was due to attend the Combined Breast Clinic the following week and was hoping that the chemotherapy would soon be stopped because the breast tumour had shrunk enough and then start a course of radiotherapy.

At Interview 5 Mrs B. had stopped chemotherapy and was receiving radiotherapy on a daily basis for a two week period. She said that she was feeling much more in control and she and her husband were planning a short holiday after finishing her course of radiotherapy. She had noticed that her hair was beginning to grow back and this pleased her. She was still using the relaxation tape on a regular basis but said that it had become a habit rather than really needing it. She had been discharged from the Clinical Psychologist but she could contact him if she found she were becoming distressed again in the future. She found this reassuring to know that he was there if she needed to speak to him. There were no major problems at that time and she seemed content with life although she continued to feel tired and the skin on her breast was tender and red (it did not please her that she could not bathe during her two-week course of radiotherapy).

This pattern of improvement continued over the next interview period. However, at Interview 8 Mrs B. said that she had been having bad headaches and she had been admitted for further investigations. Brain metastases were detected on a scan and Mrs B. was to receive further chemotherapy. This had not yet commenced at the eighth interview and she was still able to work. She said that she was worried about the spread of the disease but was more concerned about having further chemotherapy.

Table 2 outlines Mrs B's scores on the Hospital Anxiety and Depression scale (HAD), the Cancer Rehabilitation Evaluation System (CARES) global score and the Edinburgh rehabilitation status scale (ERSS) total score.

Table 2

Mrs B's scores on the HAD, CARES and ERSS at each interview

Interview	HAD anxiety	HAD depression	CARES global	ERSS total
1	3	4	0.31	1
2	14	12	1.21	10
3	11	6	0.86	9
4	5	2	0.67	9
5	5	2	0.67	9
6	6	2	0.40	8
7	5	2	0.67	8
8	6	2	0.86	9

It can be seen from Table 2 that there was a marked increase in the HAD scores at Interviews 2 and 3, and using the cut-off scores suggested by the authors [Zigmond and Snaith, 1983] scored in the "case" range on anxiety at Interview 2 and 3 and in the "case" range on depression at Interview 2. There was also a marked increase in the CARES global score and ERSS total score at Interview 2. The authors of the ERSS [Affleck et al. 1988] suggest that total scores can give an indication of level of functioning and also give a percentage level of dysfunction. Using these, the ERSS total scores of Mrs B can be interpreted to indicate that her level of functioning at Interviews 1 was high (4 per cent dysfunction). However, at Interview 2 this increased to a "moderate" level of functioning (36 per cent dysfunction). This reduced slightly at subsequent interviews but remained within the range of "moderate" dysfunction.

(3) **Mrs C.** was a 60 year old lady with a son and daughter no longer living at home. She had recently retired as a legal secretary and was married (her husband recently having had a stroke). She had been treated for primary breast cancer six years previously and had undergone surgery and radiotherapy. For the previous three months she had been having increasing back pain. Her general practitioner referred her to Longmore Hospital for re-staging of her breast cancer. Metastatic disease was confirmed; bony metastatic deposits being found in the lumbar spine. She was referred to the Combined Breast Clinic at Longmore Hospital and was prescribed Tamoxifen.

At Interview 1, Mrs C reported that she was getting some pain, but that she was still able to do all the things she was previously able to do. She had slight difficulty bending down to pick items off the floor and also use the vacuum cleaner as it was quite heavy. She was able to do all the shopping. Her main problem concerned her relationship with her husband who had serious speech difficulties due to his stroke and she found him rather unsympathetic to her needs. She made a point each day to meet a different friend for lunch or coffee in order to get her out of the house and have some independence. Other problems related to her weight (she had put on a lot of weight since the menopause), and constipation but she did not think that they had bore any relation to her disease. She said that she sometimes worried about the disease but she knew how to cope with her worries.

The other seven interviews took on the same pattern as Mrs C's condition did not change over the period of the study. This is reflected in Mrs C's scores at each interview (Table 3) with only minor changes.

Table 3

Mrs C's scores on the HAD, CARES and ERSS at each interview

Interview	HAD anxiety	HAD depression	CARES global	ERSS total
1	6	3	0.75	6
2	5	4	0.98	7
3	6	4	0.93	7
4	2	2	0.90	7
5	2	2	0.93	7
6	2	2	0.81	6
7	2	2	0.85	6
8	2	3	0.93	7

It can be seen from Table 3 that the scores on the HAD scores indicate low levels of anxiety and depression at each interview. Similarly, the CARES and ERSS scores at each interview indicate high levels of function. Using the suggestions of the authors of the ERSS [Affleck et al. 1988] to indicate percentage dysfunction, Mrs C's was, approximately, 25 per cent throughout the course of the study.

SECTION B

CHARACTERISTICS OF THE SAMPLE (DESCRIPTIVE DATA)

Sex

All 80 patients recruited to the study were female.

Age

The mean age of the eighty patients recruited to the main descriptive study was 53.75 years, the standard deviation being 10.26, ranging from 31 years to 72 years.

Marital Status

The majority of patients were married, with only a small number being separated or divorced, widowed or single (Table 4). In addition, few patients (n=11) were living on their own.

Table 4

Marital Status of Patients (n=80)

MARITAL STATUS	Number	%
Married	64	80.00
Separated/Divorced	2	2.50
Widowed	7	8.75
Single	7	8.75
Total	80	100.00

Social Class

The social class of patients in the study was coded using the Office of Population, Consenses and Surveys [1980] classification of occupations. This divides social class into five subdivisions (1-5: 1 signifying professional to 5 signifying unskilled). The majority of patients in the descriptive study were in the skilled category (Table 5).

Table 5

Distribution of patient's social class

Social Class		Number	%
1	Professional	6	7.50
2	Intermediate	20	25.00
3	Skilled	37	46.25
4	Semi-skilled	9	11.25
5	Unskilled	8	10.00
Total		80	100.00

Number and age of children of patients living at home

The interview schedule gathered information on the number of children the patient had, the age of the youngest child, and the number of children living at home with the patient (Tables 6-8).

Table 6

The distribution of patient's number of children

Number of children	Number	%
no children	14	17.5
one child	10	12.50
two children	41	51.25
three children	12	15.00
four children	3	3.75
Total	80	100.00

Table 6 shows that the majority of patients had two children.

Table 7

The distribution of the age of patient's youngest child

Age of the youngest child	Number	%
less than 5 years	2	2.50
between 5-10 years	6	7.50
between 10-18 years	5	6.25
older than 18 years	53	66.25
Not applicable	14	17.50
Total	80	100.00

Table 7 shows that the majority of patients had children who were older than 18 years of age.

Table 8

The number of patients with children living at home

Number of children living at home	Number	%
None	57	71.25
One child	14	17.50
Two children	6	7.50
Three children	2	2.50
Four children	1	1.25
Total	80	100.00

Table 8 shows that the majority of patients had no children living with them at home.

Time since initial diagnosis of breast cancer

The time since initial diagnosis of breast cancer was categorised into one of four categories: under three months; between three months and one year; between one and five years; and over five years. Those patients who had been diagnosed in the previous three months were those patients whose first contact with the medical team regarding breast cancer were at the outset staged as having metastatic breast cancer (Table 9).

Table 9

Time since initial diagnosis of breast cancer (n=80)

Time since initial diagnosis	Number	%
<3 months	19	23.75
3 months - 1 year	10	12.50
1 year - 5 years	33	41.25
>5 years	18	22.50
Total	80	100.00

Table 9 shows that the majority of patients had been diagnosed to have primary breast cancer between one and five years before the diagnosis of metastatic breast cancer.

Original treatment received by patients at initial diagnosis of breast cancer

The first line treatment that patients received at initial diagnosis was categorised into surgery alone, surgery and adjuvant chemotherapy, surgery and adjuvant radiotherapy, surgery and adjuvant chemotherapy and radiotherapy, chemotherapy and radiotherapy, hormone therapy, radiotherapy, chemotherapy and no treatment (Table 10).

Table 10

First Line Treatment at Diagnosis of Breast Cancer (n=80)

Initial Treatment	Number	%
Surgery alone	16	20.00
Surgery and chemotherapy	11	13.75
Surgery and radiotherapy	22	27.50
Surgery, radiotherapy and chemotherapy	9	11..25
Chemotherapy and radiotherapy	2	2.50
Hormone therapy	1	1.25
Radiotherapy	1	1.25
No treatment	18	22.50
Total	80	100.00

Table 10 shows that the majority of patients received a combination of surgery and radiotherapy as first line treatment of breast cancer.

Site of metastatic breast cancer

The site of metastatic breast cancer was categorised into one of five categories: bone; liver; lung; bone and one vital organ (lung, brain, or liver): or two vital organs. The distribution of site of metastasis is shown in Table 11.

Table 11

The distribution of the metastatic site

Site of metastasis	Number	%
Bone	33	41.25
Liver	14	17.50
Lung	24	30.00
Bone and one vital organ	5	6.25
Two vital organs	4	5.00
Total	80	100.00

Table 11 shows that the majority of patients had bone metastases at presentation of metastatic breast cancer (n=33).

Treatment following diagnosis of metastatic breast cancer

The medical treatment patients received following definitive diagnosis of metastatic breast cancer was categorised into: hormone therapy, chemotherapy, radiotherapy, surgery, and no treatment (as some patients had not yet commenced treatment) (Table 12).

Table 12

Medical Treatment at the First Interview Following Diagnosis of Metastatic Breast Cancer (n=80)

Medical Treatment at First Interview	Number	%
Hormone Therapy	33	41.25
Chemotherapy	28	35.00
Radiotherapy	1	1.25
No Treatment	18	22.50
Total	80	100.00

It can be seen from Table 12 that at the first interview, the majority of patients received hormone therapy following diagnosis of metastatic breast cancer and that 18 patients were receiving no treatment, the reason for this being that the first interview had occurred prior to the commencement of treatment. Therefore, in order to obtain a more meaningful picture of the medical treatment patients were receiving, Table 13 details the medical treatment patients were receiving at the second interview.

Table 13

Medical Treatment at the Second Interview Following Diagnosis of Metastatic Breast Cancer (n=69)

Medical Treatment at Second Interview	Number	%
Hormone Therapy	36	52.00
Chemotherapy	31	45.00
Radiotherapy	2	3.00
Total	80	100.00

At the second interview, all patients were receiving treatment, the majority of whom were receiving hormone therapy, with a signficant number receiving chemotherapy.

Contact with medical staff

At each interview, patients were asked which members of the multidisciplinary team they had seen in the previous month. Table 14 shows the percentage of patients who had seen particular members of the medical team in the previous month.

Table 14

Medical professional contact during the month before each interview (percentages shown of those patients who had seen the relevant member of the multidisciplinary team).

INTERVIEW	1ST n=80 %	2ND n=69 %	3RD n=62 %	4TH n=57 %	5TH n=54 %	6TH n=48 %	7TH n=41 %	8TH n=36 %
hospital doctor	100	78	60	56	54	56	54	52
general practitioner	89	85	82	82	81	81	80	78
psychologist/ psychiatrist	5	6	4	6	4	2	2	3
nurse counsellor	40	23	11	23	15	13	12	16
district nurse/ health visitor	19	13	16	13	11	10	12	13
social worker	2.5	0	0	0	0	0	0	0
physiotherapist	14	0	6	0	2	2	2	3
occupational therapist	6	3	6	3	4	4	5	5

Table 14 shows the small proportion of patients who had been seen by a member of the multiprofessional team in the previous month and in particular the contact with social workers, occupational therapists and physiotherapists. For example, no patients between interviews 2 and 8 had seen a social worker in the previous month, and on average only 5 per cent of patients had seen an occupational therapist or a psychologist. The importance of these findings will be understood more fully when the results are presented from the standardised measures of mood (Hospital Anxiety and Depression Scale), rehabilitation status (Cancer Rehabilitation Evaluation System and Edinburgh Rehabilitation Status Scale) and symptomatology (the Rotterdam Symptom Checklist).

DATA FROM STANDARDISED ASSESSMENT TOOLS

The Hospital Anxiety and Depression Scale (HAD)

The mood state of patients was assessed using the Hospital Anxiety and Depression Scale (HAD) [Zigmond and Snaith, 1983]. The HAD is designed to discriminate between anxiety and depression and is made up of a 7-item anxiety subscale and a 7-item depression subscale. Each item (for example, "I can laugh and see the funny side of things") is rated on a four-point scale e.g. as much as I always do (0); not quite so much (1); definitely not so much (2); and not at all (3), giving subscale scores of 21 for depression and anxiety. This scale assesses both anxiety and depression experienced during the previous week. The mean anxiety and depression scores of patients at interviews 1-8 are shown in Table 15 and 16 respectively.

Table 15

Patients' HAD (Anxiety) Scores at Interviews 1- 8: means and standard deviations.

Interview	Number	Mean HAD (Anxiety) Score	Standard Deviation
1	80	7.24	4.56
2	69	7.54	4.16
3	62	7.57	3.89
4	57	7.47	4.04
5	54	7.89	4.02
6	48	7.44	3.87
7	41	6.85	3.79
8	36	6.56	3.91

Table 16

Patients' HAD (Depression) Scores at Interview 1-8: means and standard deviation.

Interview	Number	Mean HAD (Depression) Score	Standard Deviation
1	80	6.70	4.42
2	69	6.97	4.24
3	62	6.71	3.98
4	57	6.74	3.84
5	54	7.11	3.94
6	48	6.79	3.96
7	41	6.37	3.99
8	36	6.36	4.08

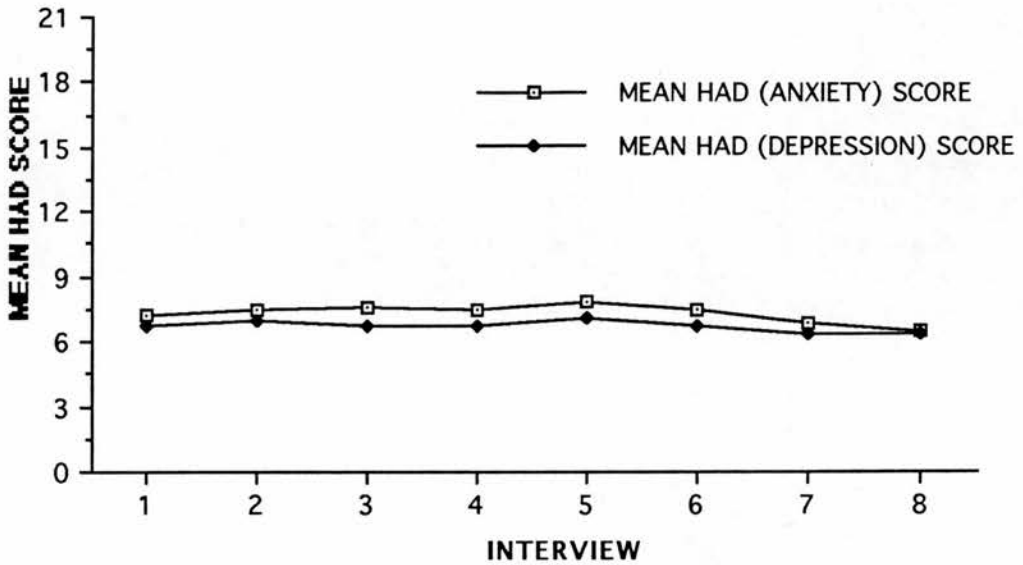
Table 17

Analysis of variance of HAD (anxiety and depression) scores for patients between interviews 1-8: F ratio and p value.

HAD SUBSCALE	F ratio	Significance
HAD (Anxiety)	0.84	p= 0.55 (N.S.)
HAD (Depression)	1.46	p= 0.18 (N.S.)

The analysis of variance described in Table 17 comparing the mean anxiety and depression levels for each interview demonstrates that there is no statistically significant difference in mood across the eight interviews. This is shown graphically in Figure 8.

FIGURE 8: MEAN HAD (ANXIETY AND DEPRESSION) SCORES AT EACH INTERVIEW



The scores of the HAD can be used to indicate "caseness". The authors, Zigmond and Snaith, have devised "cut-off" scores dividing the scale into normal (0-7), borderline (8-10), and "case" level (11-21). Tables 18-25 below show the scores of patients on the anxiety and depression subscales of the HAD at interviews 1-8 using the cut-off scores recommended by the authors [Zigmond and Snaith, 1983].

Table 18

HAD (Anxiety and Depression) scores at Interview 1 using the cut-off scores recommended by the authors (n=80).

HAD Score	Anxiety n (%)		Depression n (%)	
0-7 (normal)	46	(57.50)	45	(56.25)
8-10 (borderline)	3	(3.75)	10	(12.50)
11-21 ("case" level)	31	(38.75)	25	(31.25)

Table 19

HAD (Anxiety and Depression) scores at Interview 2 using the cut-off scores recommended by the authors (n= 69).

HAD Score	Anxiety n (%)		Depression n (%)	
0-7 (normal)	36	(51.25)	38	(55.03)
8-10 (borderline)	14	(20.18)	14	(20.27)
11-21 ("case" level)	19	(28.57)	17	(24.70)

Table 20

HAD (Anxiety and Depression) scores at Interview 3 using the cut-off scores recommended by the authors (n= 62).

HAD Score	Anxiety n (%)		Depression n (%)	
0-7 (normal)	30	(48.37)	38	(61.32)
8-10 (borderline)	12	(19.34)	12	(19.34)
11-21 ("case" level)	20	(32.29)	12	(19.34)

Table 21

HAD (Anxiety and Depression) scores at Interview 4 using the cut-off scores recommended by the authors (n= 57).

HAD Score	Anxiety n (%)		Depression n (%)	
0-7 (normal)	26	(45.55)	32	(55.99)
8-10 (borderline)	14	(24.54)	17	(29.91)
11-21 ("case" level)	17	(29.91)	8	(14.10)

Table 22

HAD (Anxiety and Depression) scores at Interview 5 using the cut-off scores recommended by the authors (n= 54).

HAD Score	Anxiety n (%)		Depression n (%)	
0-7 (normal)	22	(40.70)	28	(51.81)
8-10 (borderline)	13	(24.05)	14	(25.91)
11-21 ("case" level)	19	(35.25)	12	(22.28)

Table 23

HAD (Anxiety and Depression) scores at Interview 6 using the cut-off scores recommended by the authors (n= 48).

HAD Score	Anxiety n (%)		Depression n (%)	
0-7 (normal)	22	(45.81)	27	(56.23)
8-10 (borderline)	11	(22.91)	12	(24.98)
11-21 ("case" level)	15	(31.28)	9	(18.79)

Table 24

HAD (Anxiety and Depression) scores at Interview 7 using the cut-off scores recommended by the authors (n= 41).

HAD Score	Anxiety n (%)		Depression n (%)	
0-7 (normal)	22	(53.60)	26	(63.36)
8-10 (borderline)	11	(26.81)	9	(21.93)
11-21 ("case" level)	8	(19.59)	6	(14.71)

Table 25

HAD (Anxiety and Depression) scores at Interview 8 using the cut-off scores recommended by the authors (n= 36).

HAD Score	Anxiety n (%)		Depression n (%)	
0-7 (normal)	20	(55.55)	23	(63.89)
8-10 (borderline)	10	(27.78)	7	(19.44)
11-21 ("case" level)	6	(16.67)	6	(16.67)

Figure 9, below, illustrates the number of patients who scored in the normal range, borderline range and case range for anxiety on the HAD at each interview. This shows clearly the relatively large proportion of patients who fell into the borderline and case ranges using the cut off scores recommended by the authors.

FIGURE 9: HAD ANXIETY SCORES AT EACH INTERVIEW USING THE CUT OFF SCORES

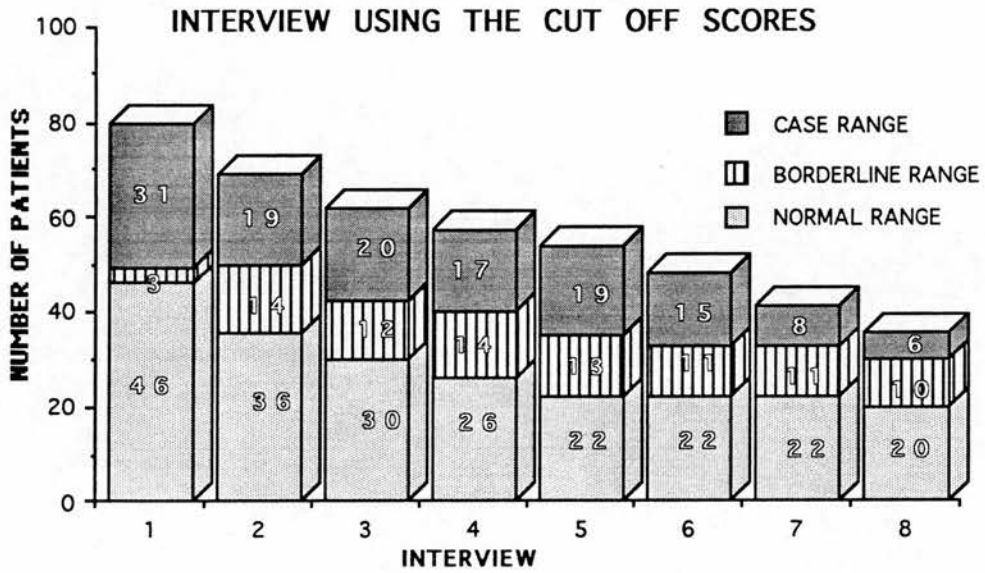
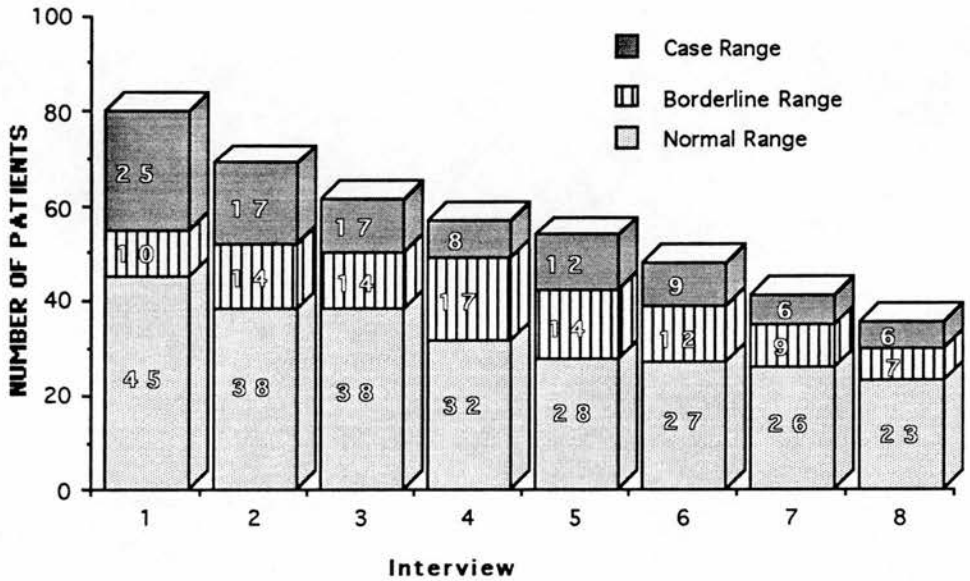


Figure 10 below illustrates the distribution of the depression scores on the HAD at each interview using the cut-off scores suggested by the authors.

FIGURE 10: HAD DEPRESSION SCORES AT EACH INTERVIEW USING THE CUT OFF SCORES



The reason for the drop in numbers at each interview (e.g. 80 at interview 1 and 36 at interview 8) was due to patients dying. It could be argued that the reason for lower mean anxiety and depression scores at Interview 8 is due to these patients being the "survivors" and higher mean scores at previous interviews is due to the intrusion of those patients who were dying and their scores "contaminated" the data from the HAD. Further analysis was conducted on the data from the "survivors" and those who died during the course of the study. The results of this analysis is presented in a Section C.

The Rotterdam Symptom Checklist (RSCL)

In addition to completing the HAD, patients completed the Rotterdam Symptom Checklist (RSCL) [de Haes and van Knippenberg, 1983] at each interview. This scale monitors symptoms in various domains: psychological e.g. depressed mood, irritable (ten items); gastro-intestinal e.g. nausea, constipation (seven items); sensory e.g. pain, tingling hands (two items); fatigue e.g. tiredness, lack of energy (three items); and miscellaneous symptoms e.g. loss of hair, short of breath (eight items). Scoring of the RSCL is problem orientated: patients are asked the degree to which they have been bothered by the indicated symptoms during the past week on a four point scale from "not at all" (scoring zero) to "very much" (scoring three) therefore higher scores indicate greater levels of symptoms. The psychological subscale score yields a maximum score of 30; gastro-intestinal 21; sensory 6; fatigue 9; and miscellaneous 24. The means and standard deviations at each interview are detailed in Tables 26-30 by domain.

Table 26

Patients RSCL (Psychological Symptoms) Scores at Interviews 1-8: means and standard deviations.

Interview	Number	Mean RSCL (Psychological) Score	Standard Deviation
1	80	7.64	6.03
2	69	8.73	5.84
3	62	7.86	4.63
4	57	8.54	5.27
5	54	8.91	5.17
6	48	8.50	4.80
7	41	7.78	4.81
8	36	7.67	5.04

Table 27

Patients RSCL (Gastro-intestinal) Scores at Interviews 1-8: means and standard deviations.

Interview	Number	Mean RSCL (Gastro-intestinal) Score	Standard Deviation
1	80	5.01	3.19
2	69	5.55	4.69
3	62	5.50	3.42
4	57	5.89	3.73
5	54	6.11	3.70
6	48	5.79	3.57
7	41	5.51	3.63
8	36	5.44	3.63

Table 28

Patients RSCL (Sensory) Scores at Interviews 1-8: means and standard deviations.

Interview	Number	Mean RSCL (Sensory) Score	Standard Deviation
1	80	0.61	0.72
2	69	0.73	1.06
3	62	0.81	1.11
4	57	1.40	2.19
5	54	1.44	2.26
6	48	1.17	1.83
7	41	1.07	1.78
8	36	0.97	1.73

Table 29

Patients RSCL (Fatigue) Scores at Interviews 1-8: means and standard deviations.

Interview	Number	Mean RSCL (Fatigue) Score	Standard Deviation
1	80	4.84	2.19
2	69	5.17	2.46
3	62	5.26	2.41
4	57	5.45	2.55
5	54	5.48	2.56
6	48	5.23	2.57
7	41	4.98	2.48
8	36	4.72	2.47

Table 30

Patients RSCL (Miscellaneous Symptom) Scores at Interviews 1-8: means and standard deviations.

Interview	Number	Mean RSCL (Miscellaneous Symptom) Score	Standard Deviation
1	80	4.42	2.69
2	69	4.73	3.26
3	62	4.69	2.91
4	57	4.71	3.16
5	54	4.59	2.95
6	48	4.27	2.76
7	41	4.00	2.76
8	36	4.08	2.81

Table 31

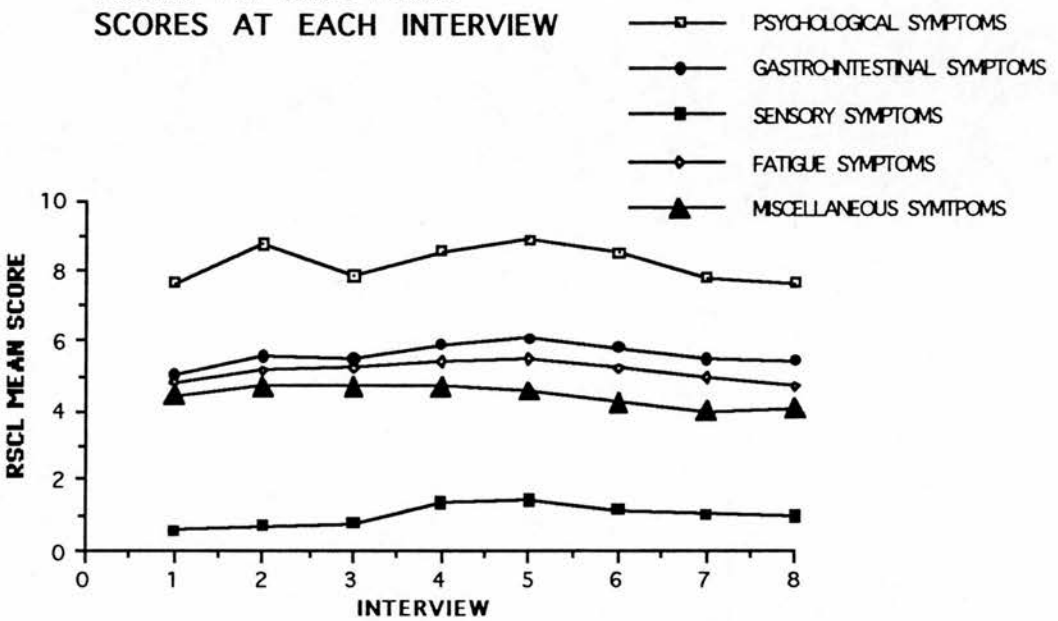
Analysis of variance of RSCL domain scores for patients between interviews 1-8: F ratios and p values.

RSCL SUBSCALE	F ratio	Significance
Psychological	2.75	p= 0.009
Gastro-intestinal	4.15	p= 0.0002
Sensory	1.63	p=0.13 (N.S.)
Fatigue	1.67	p=0.12 (N.S.)
Miscellaneous	1.09	p= 0.38 (N.S.)

Table 31 describes the analysis of variance between RSCL domain scores for patients between interviews 1 and 8 indicating that only two domains demonstrate a statistically significant difference across interviews: that of psychological and gastro-intestinal symptoms. The analysis of variance for the gastro-intestinal domain of the RSCL shows this to be significant at p= 0.002 and the Scheffé multiple range test reveals the significant difference to be between interview 1 and interview 5 (F= 2.10; df= 7; p= <0.05). The analysis of variance for the psychological domain of the RSCL demonstrated this to be significant at p= 0.009. However, the Scheffé multiple range test did not reveal any significant level of difference between the interviews suggesting that no one pair of interviews can account for the statistically significant difference seen overall with the analysis of variance.

Figure 11, below, illustrates differences is symptomatology as measured in the various subscales of the RSCL.

FIGURE 11: RSCL MEAN SCORES AT EACH INTERVIEW



The Cancer Rehabilitation Evaluation System- Short Form (CARES)

The rehabilitation status of each patient was monitored at each interview using the Cancer Rehabilitation Evaluation System- Short Form (CARES) [Schag and Heinrich, 1988]. This scale gives a global CARES score as well as giving a score for each individual subscale (physical, psychosocial, medical interaction, sexual and marital). The global score and the five subscale scores were calculated according to the authors' instructions in the CARES Manual. The raw scores of the CARES are used in the present analysis because the normative scores which were developed by the authors were conducted on a relatively small number of patients (n=150) who had primary breast cancer. In a recent paper published by the authors [Ganz et al., 1992] they recognise the shortcomings of the normative scores for patient groups and recommend use of the raw scores of the CARES. Since the CARES is problem orientated, a lower raw score indicates fewer and/ or less severe problems.

Table 32

Patients CARES Global Scores at Interviews 1-8: means and standard deviations.

Interview	Number	Mean CARES Global Score	Standard Deviation
1	80	0.92	0.64
2	69	0.95	0.56
3	62	0.93	0.49
4	57	0.92	0.48
5	54	0.95	0.50
6	48	0.88	0.45
7	41	0.82	0.44
8	36	0.80	0.46

Table 33

Patients CARES (Physical) Scores at Interviews 1-8: means and standard deviations.

Interview	Number	Mean CARES (Physical) Score	Standard Deviation
1	80	1.16	0.69
2	69	1.29	0.85
3	62	1.36	0.77
4	57	1.28	0.68
5	54	1.28	0.68
6	48	1.23	0.68
7	41	1.15	0.66
8	36	1.15	0.68

Table 34

Patients CARES (Psychosocial) Scores at Interviews 1-8: means and standard deviations.

Interview	Number	Mean CARES (Psychosocial) Score	Standard Deviation
1	80	1.05	0.70
2	69	1.53	0.67
3	62	1.11	0.63
4	57	1.09	0.62
5	54	1.11	0.62
6	48	1.08	0.62
7	41	1.01	0.63
8	36	1.01	0.65

Table 35

Patients CARES (Medical Interaction) Scores at Interviews 1-8: means and standard deviations.

Interview	Number	Mean CARES (Medical Interaction) Score	Standard Deviation
1	80	0.47	0.56
2	69	0.43	0.58
3	62	0.26	0.36
4	57	0.34	0.73
5	54	0.32	0.74
6	48	0.22	0.37
7	41	0.19	0.33
8	36	0.19	0.34

Table 36

Patients CARES (Sexual) Scores at Interviews 1-8: means and standard deviations.

Interview	Number	Mean CARES (Sexual) Score	Standard Deviation
1	80	1.34	1.60
2	69	1.40	1.53
3	62	1.19	1.32
4	57	1.06	1.27
5	54	1.07	1.29
6	48	0.81	1.06
7	41	0.68	0.99
8	36	0.61	0.97

Table 37

Patients CARES (Marital) Scores at Interviews 1-8: means and standard deviations.

Interview	Number	Mean CARES (Marital) Score	Standard Deviation
1	80	0.32	0.59
2	69	0.38	0.53
3	62	0.31	0.47
4	57	0.41	0.59
5	54	0.42	0.61
6	48	0.40	0.63
7	41	0.30	0.49
8	36	0.25	0.37

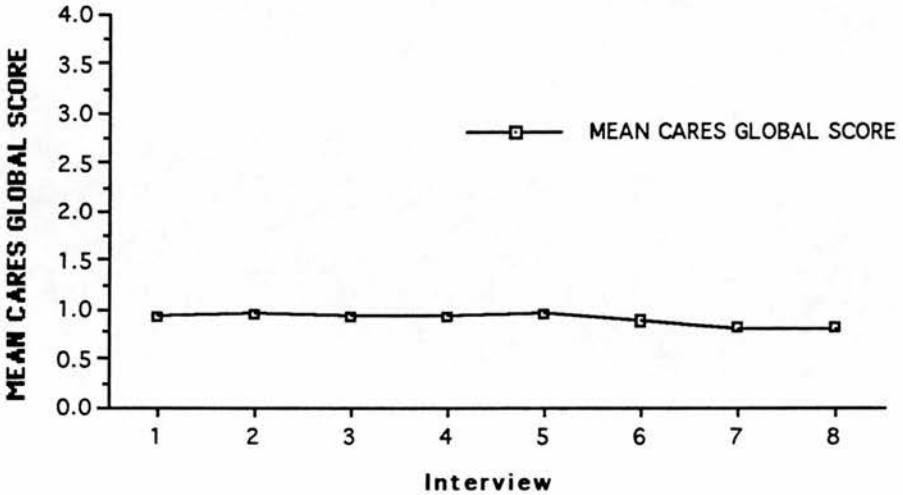
Table 38

Analysis of variance of CARES global and domain scores for patients between interviews 1-8: F ratios and p values.

CARES	F ratio	Significance
Global Score	0.42	p= 0.89 (N.S.)
Physical Domain	2.16	p= 0.04
Psychosocial Domain	3.10	p= 0.004
Medical Interaction Domain	1.09	p= 0.37 (N.S.)
Sexual Domain	2.21	p= 0.03
Marital Domain	0.77	p= 0.61 (N.S.)

Table 38, describing the analysis of variance between CARES domain scores for patients between interviews 1 and 8, indicates that the only three domains which demonstrate a statistically significant difference across interviews are that of the physical, the psychosocial and sexual domains. The analysis of variance for the physical domain shows this to be significant at p= 0.04. The Scheffé multiple range test, however, did not reveal any significant level of difference between the interviews, suggesting that no one pair of interviews can account for the statistically significant difference seen overall with the analysis of variance. The analysis of variance for the psychosocial domain demonstrated this to be significant at p= 0.004 and the Scheffé multiple range test reveals the significant difference to be between interview 1 and interview 2 (F= 2.69; df= 7; p= <0.05). The analysis of variance for the sexual domain demonstrated this to be significant at p= 0.03. However, the Scheffé multiple range test did not reveal any significant level of difference between the interviews suggesting that no one pair of interviews can account for the statistically significant difference seen overall with the analysis of variance. Figure 12 illustrates the mean CARES global scores at each interview.

FIGURE 12: MEAN CARES GLOBAL SCORES AT EACH INTERVIEW



The Edinburgh Rehabilitation Status Scale (ERSS)

The researcher also completed the Edinburgh Rehabilitation Status Scale (ERSS). This scale gives a total score and four subscale scores: support (the frequency and extent to which the patient relies on others); inactivity (the ability to initiate, sustain and effectively perform activities); isolation (involvement in roles, and relationships); and effects of symptoms on lifestyle (the extent to which the severity and constancy of symptoms and impairments affect the individual's lifestyle). Scoring of the ERSS is problem-orientated; each subscale has eight levels (0-7) with the higher scores representing greater disablement. Each subscale is graded from zero to seven; zero where there is no abnormality and seven when the degree of disability is extreme in this dimension. The means and standard deviations of the total ERSS scores and the four subscales are shown in Tables 39- 44.

Table 39

Patients ERSS Total Scores at Interview 1-8: means and standard deviations.

Interview	Number	Mean ERSS Total Score	Standard Deviation
1	80	7.24	6.16
2	69	6.69	3.53
3	62	8.08	4.95
4	57	9.39	5.42
5	54	6.32	3.51
6	48	5.96	3.52
7	41	6.05	3.63
8	36	5.97	3.73

Table 40

Patients ERSS (Support Subscale) Scores at Interviews 1-8: means and standard deviations.

Interview	Number	Mean ERSS(Support Subscale) Score	Standard Deviation
1	80	2.06	1.59
2	69	1.94	1.08
3	62	2.23	1.48
4	57	2.51	1.62
5	54	1.67	1.17
6	48	1.52	1.13
7	41	1.44	1.03
8	36	1.47	1.08

Table 41

Patients ERSS (Inactivity Subscale) Scores at Interviews 1-8: means and standard deviations.

Interview	Number	Mean ERSS(Inactivity Subscale) Score	Standard Deviation
1	80	1.73	1.57
2	69	1.65	1.03
3	62	2.21	1.37
4	57	2.74	1.55
5	54	2.00	1.08
6	48	1.94	1.08
7	41	2.05	1.18
8	36	1.92	1.16

Table 42

Patients ERSS (Isolation Subscale) Scores at Interviews 1-8: means and standard deviations.

Interview	Number	Mean ERSS (Isolation Subscale) Score	Standard Deviation
1	80	0.87	1.56
2	69	0.36	0.54
3	62	0.57	1.00
4	57	0.59	0.79
5	54	0.22	0.46
6	48	0.21	0.46
7	41	0.02	0.16
8	36	0.11	0.32

Table 43

Patients ERSS (Effect of Symptoms Subscale) Scores at Interviews 1-8: means and standard deviations.

Interview	Number	Mean ERSS (Effect of Symptoms Subscale) Score	Standard Deviation
1	80	2.65	1.89
2	69	2.69	1.45
3	62	3.08	1.61
4	57	3.58	1.88
5	54	2.48	1.31
6	48	2.31	1.26
7	41	2.56	1.58
8	36	2.47	1.46

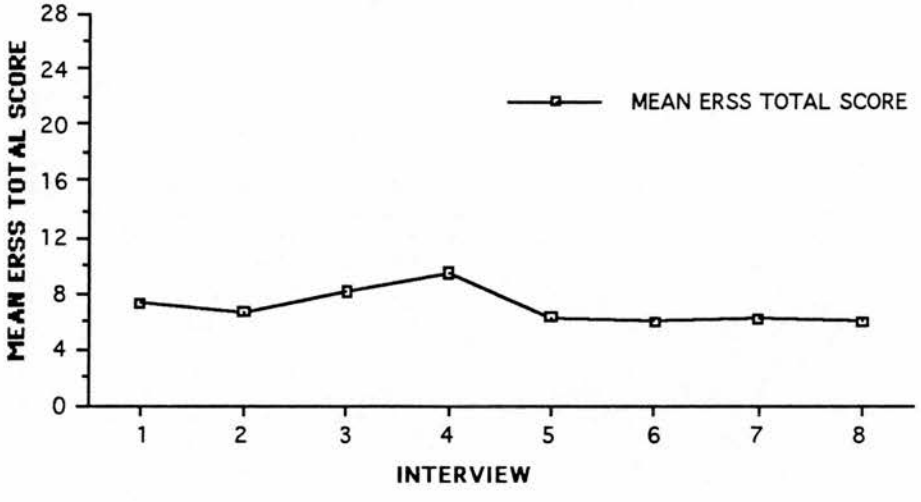
Table 44

Analysis of variance of ERSS total and subscale scores for patients between interviews 1-8: F ratios and p values.

ERSS	F ratio	Significance
Total score	6.96	p=0.0001
Support subscale	4.64	p=0.0001
Inactivity subscale	9.92	p=0.0001
Isolation subscale	3.02	p=0.005
Effect of Symptoms subscale	6.39	p=0.0001

Table 44, describing the analysis of variance between ERSS total scores for patients between interviews 1 and 8, indicates a statistically significant difference across interviews. The analysis of variance for the ERSS total score shows this to be significant at p= 0.0001 and the Scheffé multiple range test reveals the significant difference to be between interview 2 and interview 4 (F= 5.08; df= 7; p= <0.05). In addition the analysis of variance between the ERSS support subscale scores between interviews 1 and 8, indicates a statistically significant difference across interviews. The analysis of variance for the support subscale score of the ERSS shows this to be significant at p= 0.0001 and the Scheffé multiple range test reveals the signficant difference to be between interviews 1 and 4 (F= 2.05; df= 7; p= <0.05). The analysis of variance between the ERSS inactivity subscale scores between interviews 1 and 8 indicates a statistically significant difference across interviews. The analysis of variance for the inactivity subscale score of the ERSS shows this to be significant at p= 0.0001 and the Scheffé multiple range test reveals the significant difference to be between interviews 1 and 3 (F= 3.49; df= 7; p<0.05), 1 and 4 (F= 8.04; df= 7; p<0.05), 1 and 5 (F= 2.27; df= 7; p<0.05), 1 and 6 (F= 2.65; df= 7; p<0.05), 1 and 7 (F= 3.49; df= 7; p<0.05), and 1 and 8 (F= 2.85; df= 7; p<0.05). The analysis of variance between the isolation subscale between interviews 1 and 8 indicates a statistically significant difference across interviews. The analysis of variance for the isolation subscale score of the ERSS shows this to be significant at p = 0.005. However, the Scheffé multiple range test did not reveal any significant difference between the interviews suggesting that no one pair of interviews can account for the statistically significant difference seen overall with the analysis of variance. The analysis of variance between the effect of symptoms on lifestyle subscale between interviews 1 and 8 indicates a statistically significant difference across interviews. The analysis of variance for the effect of symptoms on lifestyle subscale score of the ERSS shows this to be significant at p = 0.0001 and the Scheffé multiple range test revealed the significant difference to be between interviews 1 and 3 (F=3.69; df=7; p<0.05) and 1 and 4 (F= 4.49; df= 7; 0 <0.05). Figure 13 illustrates the mean ERSS total scores at each interview.

FIGURE 13: MEAN ERSS TOTAL SCORES AT EACH INTERVIEW



The authors of the ERSS [Affleck et al. 1988] suggest that total scores can give an indication of level of functioning and also give a percentage level of dysfunction. Using these, the mean ERSS total scores can be interpreted to indicate that the mean level of functioning at Interviews 1-3 was high (25-29 per cent dysfunction). At Interviews 4 the mean level of functioning was moderate but noticeable (32 per cent dysfunction) and at Interviews 5-8 the mean level of functioning was high (21 per cent dysfunction).

SECTION C

ANALYSIS OF THE DATA FROM THOSE PATIENTS WHO SURVIVED THROUGHOUT THE COURSE OF THE DESCRIPTIVE STUDY

Further analysis was conducted on the data obtained from patients who survived throughout the course of the descriptive study (n=36). It was thought appropriate to analyse this data in an additional data set, in order to examine, in more detail, the rehabilitation status of these patients and determine levels of symptomatology, anxiety and depression. In addition, information is given regarding their demographic details.

Age

The mean age of the "survivors" was 59.3 years, the standard deviation being 7.39, ranging from 45 to 72 years.

Marital status and social class

The majority of patients were married (n=28) and belonged to social class 3 (skilled).

Number and age of children

The majority of patients had two children (n=17) and majority of patients had children who were older than 18 years of age (n= 17).

Time since initial diagnosis of breast cancer and treatment

The majority of these "survivors" had been diagnosed between 1 and 5 years previously (n= 16). However, a significant number had been diagnosed more than five years previously (n= 12).

The majority of "survivors" had received surgery and radiotherapy (n=14) as treatment at original presentation.

Site of metastasis and current medical treatment

The majority of the "survivors" had bone metastases (n= 22) and the majority of patients were receiving hormone therapy (n= 25).

DATA FROM THE STANDARDISED QUESTIONNAIRES OF THE SURVIVORS

The Hospital Anxiety and Depression Scale (HAD)

Table 45

"Survivors" HAD (Anxiety) Scores at Interviews 1- 8: means and standard deviations.

Interview	Number	Mean HAD (Anxiety) Score	Standard Deviation
1	36	5.97	4.35
2	36	6.58	4.37
3	36	6.53	4.04
4	36	6.25	3.89
5	36	6.50	3.88
6	36	6.58	3.87
7	36	6.50	3.87
8	36	6.56	3.91

Table 46

"Survivors"' HAD (Depression) Scores at Interview 1-8: means and standard deviation.

Interview	Number	Mean HAD (Depression) Score	Standard Deviation
1	36	5.19	4.05
2	36	5.86	3.91
3	36	6.19	4.21
4	36	6.00	4.15
5	36	6.17	4.19
6	36	6.19	4.18
7	36	6.17	4.19
8	36	6.36	4.08

Table 47

Analysis of variance of HAD (anxiety and depression) scores for the "survivors" between interviews 1-8: F ratio and p value.

HAD SUBSCALE	F ratio	Significance
HAD (Anxiety)	0.86	p= 0.53 (N.S.)
HAD (Depression)	1.32	p = 0.25 (N.S.)

The analysis of variance described in Table 47 comparing the mean anxiety and depression levels for each interview of the "survivors" demonstrates that there is no statistically significant difference in mood across the eight interviews.

Using the cut-off scores suggested by the authors of the HAD [Zigmond and Snaith, 1983], Table 45 below show the scores of the "survivors" on the anxiety and depression subscales of the HAD at interviews 1-8.

Table 48

HAD (Anxiety and Depression) scores of the "survivors" at Interview 1-8 using the cut-off scores recommended by the authors (n=36).

	HAD Score	Anxiety		Depression	
		n	(%)	n	(%)
HAD 1	0-7 (normal)	24	66.67	24	66.67
	8-10 (borderline)	3	8.33	4	11.11
	11-21 ("case" level)	9	25.00	8	22.22
HAD 2	0-7 (normal)	22	61.11	24	66.67
	8-10 (borderline)	6	16.67	5	13.89
	11-21 ("case" level)	8	22.22	7	19.44
HAD 3	0-7 (normal)	22	61.11	24	66.67
	8-10 (borderline)	5	13.89	5	13.89
	11-21 ("case" level)	9	25.00	7	19.44
HAD 4	0-7 (normal)	21	58.33	24	16.67
	8-10 (borderline)	9	25.00	7	19.44
	11-21 ("case" level)	6	16.67	5	13.89
HAD 5	0-7 (normal)	20	55.55	24	66.67
	8-10 (borderline)	10	27.78	6	16.67
	11-21 ("case" level)	6	16.67	6	16.67
HAD 6	0-7 (normal)	20	55.55	24	66.67
	8-10 (borderline)	9	25.00	6	6.67
	11-21 ("case" level)	7	19.44	6	6.67
HAD 7	0-7 (normal)	21	58.83	24	66.67
	8-10 (borderline)	9	25.00	6	16.67
	11-21 ("case" level)	6	16.67	6	16.67
HAD 8	0-7 (normal)	20	55.55	23	63.89
	8-10 (borderline)	10	27.78	7	19.44
	11-21 ("case" level)	6	16.67	6	16.67

The Rotterdam Symptom Checklist (RSCL)

Table 49

"Survivors" RSCL (Psychological Symptoms) Scores at Interviews 1-8: means and standard deviations.

Interview	Number	Mean RSCL (Psychological) Score	Standard Deviation
1	36	5.69	5.10
2	36	7.33	5.78
3	36	7.17	4.86
4	36	7.44	5.15
5	36	7.67	5.04
6	36	7.72	5.00
7	36	7.67	5.04
8	36	7.67	5.04

Table 50

"Survivors" RSCL (Gastro-intestinal) Scores at Interviews 1-8: means and standard deviations.

Interview	Number	Mean RSCL (Gastro-intestinal) Score	Standard Deviation
1	36	4.39	2.76
2	36	3.86	3.67
3	36	5.08	3.29
4	36	5.31	3.85
5	36	5.44	3.69
6	36	5.47	3.67
7	36	5.44	3.69
8	36	5.44	3.63

Table 51

"Survivors" RSCL (Sensory) Scores at Interviews 1-8: means and standard deviations.

Interview	Number	Mean RSCL (Sensory) Score	Standard Deviation
1	36	0.64	0.72
2	36	0.53	0.85
3	36	0.69	0.98
4	36	0.94	1.71
5	36	0.97	1.73
6	36	0.97	1.73
7	36	0.97	1.73
8	36	0.97	1.73

Table 52

"Survivors" RSCL (Fatigue) Scores at Interviews 1-8: means and standard deviations.

Interview	Number	Mean RSCL (Fatigue) Score	Standard Deviation
1	36	4.06	1.97
2	36	4.28	2.37
3	36	4.75	2.42
4	36	4.69	2.45
5	36	4.72	2.47
6	36	4.72	2.47
7	36	4.72	2.47
8	36	4.72	2.47

Table 53

"Survivors" RSCL (Miscellaneous Symptom) Scores at Interviews 1-8: means and standard deviations.

Interview	Number	Mean RSCL (Miscellaneous Symptom) Score	Standard Deviation
1	36	4.33	2.92
2	36	3.44	2.47
3	36	4.31	2.57
4	36	4.08	2.81
5	36	4.08	2.81
6	36	4.08	2.81
7	36	4.08	2.81
8	36	4.08	2.81

Table 54

Analysis of variance of RSCL domain scores for "survivors" between interviews 1-8: F ratios and p values.

RSCL SUBSCALE	F ratio	Significance
Psychological	2.72	p = 0.01
Gastro-intestinal	4.07	p = 0.0007
Sensory	1.60	p = 0.14 (N.S.)
Fatigue	1.66	p = 0.13 (N.S.)
Miscellaneous	1.15	p = 0.33 (N.S.)

Table 54 shows the analysis of variance for the RSCL domain scores from interviews 1 to 8. The analysis of variance of the psychological domain of the RSCL between interviews 1 and 8 shows this to be statistically significant (p= 0.01). However the Scheffé multiple range test did not reveal this to be significant, therefore no two pair of interviews can account for this statistical significance. The analysis of variance of the gastro-intestinal domain of the RSCL between interviews between

intervies 1 and 8 this to be statistically significant ($p= 0.0007$). The Scheffé multiple range test found this to be significant between interviews 2 and 6 ($F= 2.10$; $df=7$; $p<0.05$).

The Cancer Rehabilitation Evaluation System - Short Form (CARES)

In order to simplify the results of the data from the "survivors", only the CARES Global scores will only be presented in table-form.

Table 55

"Survivors" CARES Global Scores at Interviews 1-8: means and standard deviations.

Interview	Number	Mean CARES Global Score	Standard Deviation
1	36	0.77	0.72
2	36	0.81	0.50
3	36	0.87	0.52
4	36	0.79	0.46
5	36	0.80	0.46
6	36	0.81	0.46
7	36	0.80	0.46
8	36	0.80	0.46

Table 56

Analysis of variance of CARES global and domain scores for patients between interviews 1-8: F ratios and p values.

CARES	F ratio	Significance
Global Score	0.44	p = 0.85 (N.S.)
Physical Domain	2.22	p = 0.04
Psychosocial Domain	3.18	p = 0.005
Medical Interaction Domain	1.10	p = 0.36 (N.S.)
Sexual Domain	2.11	p = 0.05
Marital Domain	0.80	p = 0.57 (N.S.)

Table 56 shows the results of the analysis of variance for the CARES global and subscales scores indicating two statistically significant differences across interviews: the physical; the psychosocial; and the sexual domains. The analysis of variance for the physical domain shows this to be significant at p = 0.04. The Scheffé multiple range test, however, did not reveal any signficant level of difference between the interviews, suggesting that no one pair of interviews can account for the statistically significant difference seen overall with the analysis of variance. The analysis of variance for the psychosocial domain demonstrated this to be signficant at p = 0.005 and the Scheffé multiple range test reveals the signficant difference to be between interview 1 and interview 3 (F= 2.69; df=7; p<0.05). The analysis of variance for the sexual domain demonstrated this to be significant at p = 0.05. However, the Scheffé multiple range test did not reveal any significant level of difference between the interviews suggesting that no one pair of interviews can account for the statistically signficant difference seen overall with the analysis of variance.

The Edinburgh Rehabilitation Status Scale (ERSS)

Only the ERSS total scores are presented below in Table 57 .

Table 57

"Survivors" ERSS Total Scores at Interview 1-8: means and standard deviations.

Interview	Number	Mean ERSS Total Score	Standard Deviation
1	36	4.86	4.87
2	36	5.97	3.73
3	36	7.50	5.14
4	36	8.19	5.58
5	36	5.97	3.73
6	36	5.97	3.73
7	36	5.97	3.73
8	36	5.97	3.73

Table 58

Analysis of variance of ERSS scores for the "survivors' between interviews 1 and 8: F ratio and p value.

ERSS	F ratio	Significance
Total score	7.07	p = 0.0001

Table 58 shows the analysis of variance between ERSS scores for patients between interviews 1 and 8, which indicates a statistically signficant difference across interviews. The analysis of variance for the ERSS shows this to be signficant at $p = 0.0001$ and the Scheffé multiple range test reveals the signficant difference to be between interview 1 and interview 4 ($F= 5.23$; $df= 7$; $p<0.05$).

ANALYSIS OF THE DATA FROM PATIENTS WHO DIED DURING THE COURSE OF THE STUDY

In the present study, the sample reduced from 80 patients to 36 during the course of 16 months, due to patients dying from their disease. However, further analysis can also be carried out on the data from those patients who died during the course of the study. Using the data from the last interview before death to act as a "single point", separate analysis was conducted and details were obtained regarding their demography, rehabilitation status and symptomatology of this "sub-sample".

Characteristics of the patients who died during the course of the study

Age

The mean age of the 44 patients who died during the course of the study was 49.2 years, the standard deviation being 10.1, ranging from 31 to 69 years.

Marital status

The majority of patients were married (n=36), with only a small number being separated or divorced, widowed or single.

Social Class

Using the same OPCS coding classification as in the main study, the social class of patients who died during the course of the study was coded, dividing social class into five subdivisions (1-5: 1 signifying professional to 5 signifying unskilled). The majority of patients in this analysis belonged to social class 3 (skilled category) (n=20).

Time since initial diagnosis of breast cancer

The time since initial diagnosis of breast cancer was categorised for this sub-group of patients into one of four categories: under six months;

between six months and one year; between one and five years; and over five years. The majority of patients had been diagnosed between one and five years before the diagnosis of metastatic breast cancer (n= 21).

Site of metastastic spread

The majority of patients who died during the course of the study had lung metastases (n=13). In addition a large proportion had liver metastases (n=9).

Medical treatment before death

The medical treatment patients were receiving before death was categorised into: hormone therapy, chemotherapy, radiotherapy, surgery, and no treatment. The majority of patients were receiving chemotherapy before they died (n=25).

Contact with medical staff

Patients were asked which members of the multidisciplinary team they had seen in the previous month. Table 59 below shows the medical professional contact in the previous month before the last interview before death.

Table 59

Medical professional contact during the month before last interview before death (percentages shown who had seen the relevant member of the multidisciplinary team) (n=44).

MEMBER OF MEDICAL TEAM	INTERVIEW BEFORE DEATH (%)
hospital doctor	84
general practitioner	88
psychologist/ psychiatrist	9
nurse counsellor	33
district nurse/ health visitor	34
social worker	0
physiotherapist	9
occupational therapist	7

DATA FROM THE STANDARDISED QUESTIONNAIRES OF THOSE WHO DIED DURING THE STUDY:

The Hospital Anxiety and Depression Scale (HAD)

Using the HAD, patient's levels of anxiety and depression were assessed before death. The mean anxiety and depression scores of patients at their last interview before death are shown below in Table 60.

Table 60

Patients' HAD (Anxiety and Depression) Scores at the Last Interview before Death: means and standard deviation (n=44).

	Mean Score	Standard Deviation
HAD (Anxiety)	10.50	3.50
HAD(Depression)	9.82	4.00

Using the cut-off scores recommended by the authors to indicate "caseness" [Zigmond and Snaith, 1983], Table 61 below shows the scores of patients on the anxiety and depression subscales of the HAD at the last interview before death.

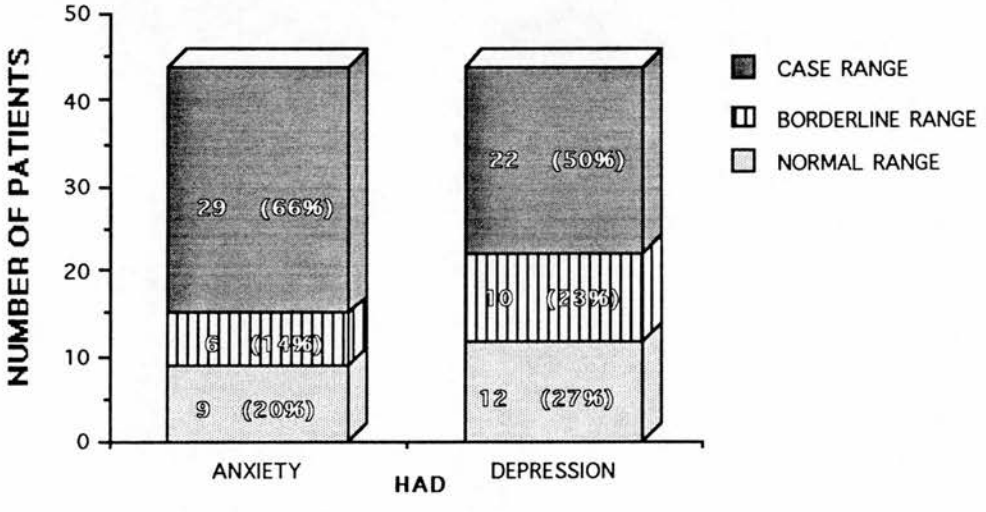
Table 61

HAD (Anxiety and Depression) scores at last interview before death using the cut-off scores recommended by the authors (n= 44).

HAD Score	Anxiety n (%)	Depression n (%)
0-7 (normal)	9 (20)	12 (27)
8-10 (borderline)	6 (14)	10 (23)
11-21 ("case" level)	29 (66)	22 (50)

An interesting finding from Table 61 above is the relatively high number of patients who scored in the "case" level range for anxiety and depression. This is illustrated in Figure 14.

FIGURE 14: HAD ANXIETY AND DEPRESSION SCORES AT THE LAST INTERVIEW BEFORE DEATH USING THE CUT OFF SCORES



The Rotterdam Symptom Checklist

Using the data obtained from the RSCL, patient's levels of symptoms (means and standard deviations) at the last interview before death are shown below in Table 62.

Table 62

Patients RSCL (Psychological Symptoms) Scores at Interviews 1-8: means and standard deviations.

RSCL DOMAIN	Number	Mean RSCL Score	Standard Deviation
psychological	44	11.70	5.95
gastro-intestinal	44	7.50	3.88
sensory	44	1.50	2.15
fatigue	44	7.11	1.95
miscellaneous symtpoms	44	6.45	3.55

The Cancer Rehabilitation Evaluation System (CARES)

Table 63

Patients CARES Global and Domain Scores (means and standard deviations) at the last interview before death.

	Number	Mean CARES Score	Standard Deviation
Global score	44	1.33	0.52
Physical score	44	1.77	0.74
Psychosocial score	44	1.42	0.58
Medical Interaction	44	0.74	0.85
Marital score	44	0.62	0.76
Sexual score	44	1.93	1.53

The Edinburgh Rehabilitation Status Scale (ERSS)

Table 64

Patients ERSS total and subscale scores (means and standard deviations) at the last interview before death.

ERSS	Number	Mean ERSS Score	Standard Deviation
Total score	44	10.02	5.15
Support subscale	44	2.57	1.70
Inactivity subscale	44	2.59	1.58
Isolation subscale	44	0.93	1.55
Effect of symptoms subscale	44	3.60	1.75

Comparison of data from those patients who died during the course of the study and the "survivors"

Comparisons of the data from the "survivors" with those patients who died during the course of the study were carried out. The reason for the comparisons were to find out whether there were any significant differences between the two groups.

Age

Table 65

Comparison of ages of the survivors and those patients who died during the course of the study: means and standard deviations

Group of patients	Number	Mean Age	Standard Deviation
Survivors	36	59.31	7.40
Patients who died	44	49.21	10.10

Using an unrelated *t* test on the data ($t = 5.00$; df=78) the results were found to be significant ($p < 0.001$). Further inspection of the results suggest that the survivors were older than those patients who died during the course of the study.

Social class and marital status

Using a chi square test, the social class and marital status of the two groups were compared to test whether they differed signficantly. The results were found not to be significant .

Site of metastatic breast cancer

The data concerning the site of metastatic breast cancer in the survivors and the patients who died was subjected to a chi square test. These results did not reach statistical significance ($X^2 = 11.46$; df = 6; p = 0.10 N.S.).

Medical treatment for the metastatic disease

The data concerning the medical treatment for the metastatic disease of the survivors and those patients who died was subjected to a chi square test. The results did achieve statistical significance ($X^2 = 15.92$; df = 3; $p < 0.01$). On closer examination of the results, it would suggest that significantly more patients who survived were receiving hormone therapy compared to those patients who died.

Comparisons of the data from standardised questionnaires

Due to the bulk of data gathered on patients, it was necessary to select items from the "survivors" and those patients who died for comparison. To this end, comparisons will be described from the HAD scale, the CARES global score and the ERSS total score. The point used for comparison for the patients who died was the last interview before death, and the point used for patients who survived was the eighth interview.

The Hospital Anxiety and Depression Scale

Table 66

Comparison of HAD anxiety scores of the survivors and those patients who died during the course of the study: means and standard deviations

Group of patients	Number	Mean HAD anxiety score	Standard Deviation
Survivors	36	5.97	4.35
Patients who died	44	10.45	3.51

Table 67

Comparison of HAD depression scores of the survivors and those patients who died during the course of the study: means and standard deviations

Group of patients	Number	Mean HAD depression score	Standard Deviation
Survivors	36	5.19	4.05
Patients who died	44	9.82	3.99

Using an unrelated *t* test on the anxiety subscale data from the HAD (*t* = -5.11; df=78), the results were found to be significant at p <0.001 for a two-tailed hypothesis. This means that the anxiety levels, as measured by the HAD, differed significantly in the two groups. Further inspection of the results suggest that those patients who died during the course of the study had higher levels of anxiety than those patients who survived throughout the course of the study.

The same test was used to analyse the depression subscale of the HAD (*t*= -5.12; df=78), the results were found to be significant at p <0.001 for a two-tailed hypothesis. This means that the depression levels, as measured by the HAD, differed significantly in the two groups. Similar to the findings of the analysis of the anxiety subscale, further inspection of the results suggest that the depression levels of those patients who died during the course of the study had higher levels of depression than those patients who survived throughout the course of the study.

Table 67a

Comparison of HAD anxiety and depression scores of the survivors (n = 36) and those patients who died after Interview 2 (n = 33) during the course of the study at Interview 1, 2 and the last interview (Interview 8 for the survivors and the last interview before death for those patients who died): means, standard deviations, *t* scores and p values).

	HAD anxiety score		Comparison of HAD anxiety score	HAD depression score		Comparisonof HAD depression score
	Mean	S.D.	*t* df p value	Mean	S.D.	*t* df p value
Interview 1 Survivors	5.97	4.34		5.19	4.05	
Interview 1 Patients who died	7.30	4.38	1.27 67 p =0.21 (N.S.)	6.85	3.77	1.75 67 p = 0.08 (N.S.)
Interview 2 Survivors	6.58	4.37		5.86	3.91	
Interview 2 Patients who died	8.57	3.71	2.03 67 p < 0.05	8.18	4.32	2.34 67 p < 0.02
Interview 8 Survivors	5.97	4.35		5.19	4.05	
Last Interview Patients who died	10.39	3.03	4.53 67 p < 0.0001	9.33	3.73	3.15 67 p < 0.002

The Cancer Rehabilitation Evaluation System

Table 68

Comparison of CARES global scores of the survivors and those patients who died during the course of the study: means and standard deviations

Group of patients	Number	Mean CARES global score	Standard Deviation
Survivors	36	0.77	0.72
Patients who died	44	1.33	0.52

Comparisons were made between the global scores of the CARES of the two groups using an unrelated *t* test. The results (t= -4.04; df =78)) were found to be significant at $p < 0.001$ for a two-tailed hypothesis. This means that the CARES global scores differed significantly in the two groups. Further inspection of the results suggest that the patients who died during the course of the study had significantly higher CARES global scores than those patients who survived.

The Edinburgh Rehabilitation Status Score

Table 69

Comparison of ERSS total scores of the survivors and those patients who died during the course of the study: means and standard deviations

Group of patients	Number	Mean ERSS total score	Standard Deviation
Survivors	36	2.94	1.04
Patients who died	44	10.02	5.15

Comparisons were made between the total scores of the ERSS of the two groups using an unrelated t test. The results (t = -8.10; df= 78) were found to be significant at $p < 0.001$ for a two-tailed hypothesis. Further inspection of the results suggest that the patients who died during the course of the study had significantly higher ERSS total scores at the last interview before death than those patients who survived at outset.

SECTION D

FACTORS WHICH CONTRIBUTE TO REHABILITATION STATUS

In order to identify contributory factors to the rehabilitation status in the total sample of patients with metastatic breast cancer, correlations were ascertained with the CARES global scores and the ERSS total scores.

The contribution of demographic variables to rehabilitation status

A range of demographic details were collected on patients and their relationship to rehabilitation status was examined. No significant associations were found between rehabilitation status as measured by the CARES global score and the ERSS total score, and the following demographic details: age, marital status, social class, number of children, the age of their children and the number of children staying at home.

The contribution of illness and treatment variables to rehabilitation status

A range of variables were collected concerning medical treatment and diagnosis and their relationship to rehabilitation status was examined. No significant associations were found between rehabilitation status as measured by the CARES global score and the ERSS total score and the following variables: time since original diagnosis; original treatment at presentation of primary breast cancer; patient's medical treatment; and patient's site of metastatic spread.

The contribution of mood to rehabilitation status

The relationship between rehabilitation status and mood state was examined. The correlations between HAD anxiety and depression scores and the CARES global scores and the ERSS total scores achieved statistical significance. The correlations are shown below (Table 70) for interview variables at the first, fourth, and eighth interview, as it was necessary to impose a structure on the data due to the bulk of data gathered.

Table 70

Correlations and levels of statistical significance between the CARES global score and ERSS total score, and HAD (anxiety and depression) score at interviews 1, 4 and 8.

SCALE	HAD SUBSCALE	r	p VALUE
ERSS 1	HAD (ANXIETY) 1	0.45	P<0.01
ERSS 1	HAD (DEPRESSION)1	0.67	P<0.001
CARES GLOBAL 1	HAD (ANXIETY) 1	0.52	P<0.001
CARES GLOBAL1	HAD (DEPRESSION) 1	0.50	P<0.01
ERSS 4	HAD (ANXIETY) 4	0.65	P<0.001
ERSS 4	HAD (DEPRESSION) 4	0.70	P<0.0001
CARES GLOBAL 4	HAD (ANXIETY) 4	0.76	P<0.0001
CARES GLOBAL4	HAD (DEPRESSION) 4	0.82	P<0.0001
ERSS 8	HAD (ANXIETY) 8	0.61	P<0.001
ERSS 8	HAD (DEPRESSION) 8	0.55	P<0.001
CARES GLOBAL 8	HAD (ANXIETY) 8	0.77	P<0.0001
CARES GLOBAL 8	HAD (DEPRESSION) 8	0.83	P<0.0001

Using Pearson product moment correlations, the results shown in Table 70 would appear to indicate that the total scores of the ERSS and the global CARES scores correlate positively with anxiety and depression as measured by the HAD, indicating that patients with higher levels of anxiety and depression have higher ERSS total scores and higher CARES global scores.

The contribution of symptomatology to rehabilitation status.

The relationship between rehabilitation status (as measured by the CARES global score and the ERSS total score) and symptomatology (as measured by the RSCL) was examined. The correlations between some subscales on the RSCL scores and the CARES global scores and the ERSS total scores achieved statistical significance. For ease of presentation, the correlations

are shown (Table 71) for interview variables at the first, fourth, and eighth interview.

Table 71

Symptoms correlated significantly with rehabilitation status at interviews 1, 4 and 8.

SCALE	SYMPTOMS	r	p VALUE
ERSS 1	RSCL (PSYCHOLOGICAL SUBSCALE)1	0.60	p<0.001
CARES 1	RSCL (FATIGUE SUBSCALE) 1	0.49	P<0.01
CARES 1	RSCL (SYMPTOM SUBSCALE) 1	0.47	P<0.01
ERSS 4	RSCL (PSYCHOLOGICAL SUBSCALE) 4	0.76	p<0.0001
ERSS 4	RSCL (FATIGUE SUBSCALE) 4	0.62	p<0.001
CARES GLOBAL 4	RSCL (FATIGUE SUBSCALE) 4	0.67	P<0.001
CARES GLOBAL 4	RSCL (GASTROINTESTINAL SUBSCALE) 4	0.79	P<0.0001
CARES GLOBAL 4	RSCL (SYMPTOM SUBSCALE) 4	0.78	P<0.0001
ERSS 8	RSCL (PSYCHOLOGICAL SUBSCALE) 8	0.64	p<0.001
ERSS 8	RSCL (GASTROINTESTINAL SUBSCALE) 8	0.50	p<0.01
ERSS 8	RSCL (FATIGUE SUBSCALE) 8	0.48	p<0.01
CARES 8	RSCL (PSYCHOLOGICAL SUBSCALE) 8	0.85	P<0.0001
CARES 8	RSCL (FATIGUE SUBSCALE) 8	0.69	P<0.001
CARES 8	RSCL (SYMPTOM SUBSCALE) 8	0.75	P<0.0001
CARES 8	RSCL (GASTROINTESTINAL SUBSCALE) 8	0.79	P<0.0001

Using Pearson product moment correlation test, the results are shown in Table 71 indicating that the ERSS total and CARES global scores correlate significantly with symptomatology measured by the RSCL.

Stepwise Multiple Regression Analysis

The variables contributing to rehabilitation status measured in patients by the ERSS total score and CARES global score were examined in more detail in order to determine the interrelationships between variables. This was achieved by an automated stepwise multiple regression analysis with alpha to enter at 0.05 level of significance and alpha to remove of 0.1 [Dillon and Goldstein, 1984]. It was necessary to impose a structure on the data from this study and, due to the large quantity of data gathered, be selective in the choice of variables to be examined. To this end, data from interviews 1, 4 and 8 were selected and, in order to satisfy the aims of the study, focus on the contribution and relationship of variables to the CARES global score and ERSS total score. All the variables assessed by the standardised measures at Interviews 1, 4, and 8 were entered, as well as certain demographic details (age, and social class).

Automated stepwise regression analysis was utilised to examine the contribution of variables to the ERSS total score at Interview 1 and the CARES global score at Interview 1. Using the CARES global score at Interview 1 as the dependent variable three variables were identified as contributing significantly (Table 72).

Table 72

Stepwise multiple regression analysis with CARES global score at Interview 1 as the dependent variable

Step	Variable entered	r	Contribution to R^2	Cumulative R^2
1	HAD(depression) 1	0.61	0.37	0.37
2	RSCL (fatigue) 1	0.71	0.14	0.51
3	RSCL (sensory) 1	0.74	0.03	0.54

The variables identified as contributing significantly to the variance of the CARES global score at Interview 1, accounting for 54 per cent of the variance, were the HAD depression score, the RSCL fatigue and sensory subscales at Interview 1 ($F=45.15$; $df=1, 79$; $p<0.001$).

Using the ERSS total score as the dependent variable, three variables were identified as contributing significantly to it (Table 73).

Table 73

Stepwise multiple regression analysis with ERSS total score at Interview 1 as the dependent variable.

Step	Variable entered	r	Contribution to R^2	Cumulative R^2
1	CARES (physical) 1	0.83	0.69	0.69
2	CARES (marital) 1	0.17	0.03	0.72
3	RSCL (sensory) 1	0.16	0.03	0.75

The three variables which were significantly associated with the ERSS total score at Interview 1, and accounted for 75 per cent of the variance, were the CARES physical and marital domain scores at Interview 1 and the sensory subscale of the RSCL at Interview 1 ($F= 177.44$; $df=1, 79$;

p<0.001). This would suggest that patients with a higher physical and marital domain score and a high score on the sensory subscale of the RSCL had a higher ERSS score at Interview 1.

The stepwise analysis of the CARES global score at Interview 4 as the dependent variable produced four variables which significantly contributed to it (Table 74).

Table 74

Stepwise multiple regression analysis using patients' CARES global score at Interview 4 as the dependent variable.

Step	Variable entered	r	Contribution to R^2	Cumulative R^2
1	Age	-0.51	0.25	0.25
2	CARES (physical) 1	0.37	0.14	0.39
3	HAD (anxiety) 1	0.67	0.06	0.45
4	RSCL (psychological) 1	0.70	0.04	0.49

The four variables which significantly contributed to the CARES global score at Interview 4 were the patient's age, the patient's CARES physical domain score, HAD anxiety score and the RSCL psychological subscale score at Interview 1. These four variables accounted for 49 per cent of the variance of the dependent variable (F= 17.44; df= 1, 52; p<0.001). This data would suggest therefore that younger patients with higher CARES physical domain scores, higher HAD anxiety scores and higher RSCL psychological subscale scores at Interview 1 had higher CARES global scores at Interview 4.

The stepwise analysis of the ERSS total score at Interview 4 as the dependent variable produced two variables which significantly contributed to it (Table 75).

Table 75

Stepwise multiple regression analysis with ERSS total score at Interview 4 as the dependent variable

Step	Variable entered	r	Contribution to R^2	Cumulative R^2
1	Age	-0.52	0.27	0.27
2	CARES (physical) 1	0.63	0.13	0.40

The variables which contributed significantly to the ERSS total score at Interview 4 were the patient's age and the CARES physical domain score at Interview 1 ($F=19.20$; $df=1, 52$; $p<0.001$) and these variables accounted for 40 per cent of the variance of the dependent variable.

The dependent variables were patients CARES and ERSS global and total scores respectively at Interview 8. Two variables emerged from this analysis as contributing to patients' CARES global scores at Interview 8 (Table 76).

Table 76

Stepwise multiple regression analysis using patients' CARES global score at Interview 8 as the dependent variable.

Step	Variable entered	r	Contribution to R^2	Cumulative R^2
1	HAD(depression) 1	0.58	0.34	0.34
2	Age	-0.67	0.11	0.45

The two variables significantly associated with the CARES global score at Interview 8 were the HAD depression score at interview 1 and the patient's age. These two variables accounted for 45 per cent of the variance of the dependent variable and in combination produced a significant association ($F= 17.53$; $df=1, 35$; $p <0.001$). This data would suggest that

younger patients with the higher depression scores at Interview 1 have the highest CARES global scores at Interview 8.

An automated stepwise procedure using the same levels of inclusion and exclusion were performed using the ERSS total scores at Interview 8 as the dependent variable (Table 77).

Table 77

Stepwise multiple regression analysis using patients' ERSS total score at Interview 8 as the dependent variable.

Step	Variable entered	r	Contribution to R^2	Cumulative R^2
1	HAD(depression) 1	0.64	0.41	0.41
2	CARES(sex) 1	0.69	0.08	0.49

In the latter analysis, the patient's HAD depression score at Interview 1 and the patient's CARES score in the sexual domain at Interview 1 emerged as contributing significantly to the patient's ERSS total score at Interview 8 ($F=24.05$; $df=1, 35$; $p<0.001$), accounting for 49 per cent of the variance of the dependent variable. This data would suggest, therefore, that patients with higher HAD depression scores and higher CARES sexual domain scores at Interview 1 would have higher ERSS total scores at Interview 8 i.e the presence of depression at diagnosis of metastatic breast cancer predicts poor rehabilitation status outcome.

Reduction of the data: factor analysis

The main descriptive study examined a large number of variables in patients with metastatic breast cancer. One method of reducing these data sets and exploring further the possible underlying structure and interrelationships between variables was to embark on a factor analysis [Child, 1990]. The variables measured from Interviews 1,4 and 8 were subjected to a factor analysis and the optimum explanation of the variance obtained (only the standardised questionnaire data were entered into the factor analysis and demographic data (age, and social class).

Using StatView [1988], the method of factor extraction was a principal component analysis which performs a simple eigenvalue-eigenvector analysis of the correlation matrix in its original form. The number of factors was restricted to those factors having an eigenvalue of one or greater than one. The data are shown as an unrotated factor matrix (Table 78) and then the data are subjected to an orthogonal, varimax rotation thus producing factors which are independent of each other (Table 79). Table 80 is included to demonstrate more clearly the nine factors, their eigenvalues and the variance they account for as a result of the rotated factor matrix.

Table 78

Unrotated factor matrix of variables associated with data from main descriptive study.

VARIABLE	Factor1	Factor2	Factor3	Factor 4	Factor5	Factor6	Factor7	Factor 8	Factor9
AGE	-0.28	-0.45	0.09	-0.01	-0.51	0.39	-0.16	-0.14	0.03
NUMBER OF CHILDREN	-0.15	0.21	-0.06	-0.04	0.65	0.05	-0.25	0.04	-0.24
SOCIAL CLASS	0.18	0.25	0.07	0.22	0.19	-0.31	0.74	-0.19	0.08
HAD(ANX) 1	0.71	-0.39	-0.01	0.14	-0.04	-0.46	-0.13	-0.11	-0.07
HAD(DEP)1	0.73	-0.49	0.19	0.07	-0.11	-0.10	-0.18	0.15	0.01
CARES (PHYS)1	0.71	-0.33	0.37	-0.28	-0.19	0.15	0.08	0.04	0.11
CARE (PSYCHO) 1	0.59	-0.37	0.26	-0.35	0.19	-0.04	0.31	-0.03	-0.22
CARES (MED.INT.)1	0.44	-0.16	0.44	-0.29	0.15	0.45	0.19	0.14	-0.20
CARES (SEXUAL) 1	0.15	0.54	0.53	-0.12	0.34	-0.31	-0.04	0.06	0.11
CARES GLOBAL 1	0.41	-0.17	0.54	-0.17	0.23	-0.37	-0.16	0.01	-0.28
RSCL (PSYCH) 1	0.55	-0.51	0.31	-0.04	-0.21	-0.22	-0.02	-0.12	0.31
RSCL(GI) 1	0.52	-0.01	0.33	0.44	0.09	0.19	-0.33	-0.18	0.29
RSCL (SENSORY)1	-0.14	0.28	0.31	0.51	0.18	-0.26	-0.27	-0.23	-0.01
RSCL (FATIGUE)1	0.40	-0.07	0.56	0.01	0.44	0.06	-0.02	0.25	0.31
RSCL (MISCELL) 1	0.26	-0.17	0.74	0.21	0.24	0.01	0.03	-0.25	0.09
ERSS 1	0.58	-0.47	0.41	-0.36	-0.01	0.22	0.09	-0.04	-0.12
HAD(ANX) 4	0.87	-0.23	-0.16	0.19	-0.13	-0.25	-0.03	0.06	-0.06
HAD(DEP)4	0.88	-0.09	-0.18	-0.05	-0.02	0.05	-0.10	0.13	0.13
CARES (PHYS)4	0.85	0.30	-0.26	-0.02	-0.01	0.11	0.07	-0.19	-0.09
CARES (PSYCHO) 4	0.94	-0.03	-0.13	-0.09	-0.01	0.03	-0.08	0.03	-0.07

Table 78 continued.....

CARES (PSYCHO) 4	0.94	-0.03	-0.13	-0.09	-0.01	0.03	-0.08	0.03	-0.07
CARES (MED.INT.)4	0.43	-0.35	-0.40	0.22	0.49	0.38	-0.05	-0.13	0.09
CARES (SEXUAL) 4	0.53	0.62	0.06	-0.39	-0.05	0.14	-0.11	0.03	0.24
CARES GLOBAL 4	0.93	0.19	-0.14	-0.11	-0.03	0.04	-0.09	-0.12	-0.09
RSCL (PSYCH) 4	0.88	0.02	-0.21	0.11	-0.10	-0.27	-0.03	0.11	-0.13
RSCL(GI) 4	0.83	-0.05	-0.19	0.16	0.19	0.06	0.09	-0.22	-0.10
RSCL (SENSORY)4	0.27	0.26	0.40	0.60	-0.26	0.32	0.07	0.28	-0.23
RSCL (FATIGUE)4	0.80	0.03	-0.11	0.19	-0.08	-0.04	0.30	0.29	0.22
RSCL (MISCELL) 4	0.78	0.37	0.21	0.01	-0.12	0.11	0.08	-0.22	-0.07
ERSS 4	0.83	0.45	0.01	-0.01	-0.19	-0.01	-0.17	-0.01	-0.04
HAD(ANX) 8	0.86	-0.26	-0.18	0.13	-0.1	-0.19	-0.07	0.12	0.05
HAD(DEP)8	0.86	-0.10	-0.19	-0.08	0.02	-0.02	-0.06	0.19	0.13
CARES (PHYS)8	0.86	0.29	-0.28	-0.03	0.02	0.13	0.06	-0.15	-0.05
CARES (PSYCHO) 8	0.94	-0.03	-0.13	-0.10	0.02	0.02	-0.06	0.05	-0.08
CARES (MED.INT.)8	0.43	-0.35	-0.40	0.22	0.49	0.38	-0.05	-0.13	0.09
CARES (SEXUAL) 8	0.53	0.61	0.06	-0.39	-0.05	0.14	-0.11	0.03	0.24
CARES GLOBAL 8	0.94	0.17	-0.16	-0.12	0.01	0.03	-0.09	-0.06	-0.05
RSCL (PSYCH) 8	0.89	-0.01	-0.22	0.08	-0.06	-0.24	-0.06	0.17	-0.06
RSCL (GI) 8	0.84	-0.06	-0.22	0.13	0.25	0.06	0.09	-0.14	-0.08
RSCL (SENSORY)8	0.29	0.21	0.41	0.64	-0.26	0.31	0.07	0.22	-0.18
RSCL (FATIGUE) 8	0.81	0.02	-0.09	0.19	-0.09	-0.04	0.30	0.27	0.23
RSCL (MISCELL) 8	0.78	0.37	0.21	0.01	-0.12	0.11	0.08	-0.21	-0.07
ERSS 8	0.78	0.13	0.26	-0.10	-0.12	-0.07	-0.22	-0.16	-0.14
VARIABLE	**Factor1**	**Factor2**	**Factor3**	**Factor 4**	**Factor5**	**Factor6**	**Factor7**	**Factor 8**	**Factor9**

Table 79

Varimax rotated factor matrix of variables associated with data from main descriptive study.

VARIABLE	Factor 1	Factor2	Factor3	Factor 4	Factor5	Factor6	Factor7	Factor 8	Factor9
AGE	-0.27	-0.23	0.13	0.13	***0.57***	0.02	-0.49	-0.15	-0.05
NUMBER OF CHILDREN	-0.05	-0.14	-0.03	-0.01	***-0.86***	0.14	-0.12	0.02	0.04
SOCIAL CLASS	0.06	0.06	0.01	0.07	0.05	-0.01	***0.92***	0.09	0.01
HAD(ANX) 1	-0.04	***0.86***	0.19	-0.11	0.13	0.05	0.04	0.3	-0.13
HAD(DEP)1	-0.03	***0.76***	0.44	0.11	0.14	0.08	-0.21	0.18	0.12
CARES (PHYS)1	0.28	0.44	***0.71***	0.07	0.30	0.01	-0.09	0.01	0.22
CARE (PSYCHO) 1	0.09	0.38	***0.79***	-0.13	-0.02	0.08	0.22	-0.3	-0.08
CARES (MED.INT.)1	0.24	0.02	***0.82***	0.24	-0.09	0.15	-0.03	-0.09	0.06
CARES (SEXUAL) 1	0.34	-0.09	0.13	-0.03	-0.41	-0.35	0.27	0.50	0.20
CARES GLOBAL 1	0.03	0.35	***0.57***	-0.08	-0.25	-0.25	-0.01	0.46	-0.14
RSCL (PSYCH) 1	-0.04	***0.55***	0.43	-0.11	0.47	-0.05	-0.04	0.29	0.25
RSCL (GI) 1	0.26	0.29	0.07	0.34	0.17	0.34	-0.15	0.61	0.23
RSCL (SENSORY)1	-0.06	-0.11	-0.31	0.19	-0.12	-0.07	0.08	***0.69***	-0.12
RSCL (FATIGUE)1	0.11	0.13	0.50	0.11	-0.26	0.11	0.07	0.42	***0.54***
RSCL (MISCELL) 1	-0.02	-0.02	***0.51***	0.21	0.12	0.08	0.16	***0.68***	0.10
ERSS 1	0.13	0.29	***0.88***	-0.01	0.19	0.11	-0.11	0.01	0.01
HAD(ANX) 4	0.15	***0.93***	0.13	0.09	0.11	0.14	0.07	0.05	-0.04
HAD(DEP)4	0.41	***0.74***	0.19	0.03	0.02	0.27	-0.08	-0.06	0.18
CARES (PHYS)4	***0.67***	***0.53***	0.05	0.09	0.03	0.30	0.19	-0.08	-0.17
CARES (PSYCHO) 4	0.49	***0.74***	0.28	0.05	-0.02	0.23	-0.03	-0.04	-0.03

Table 79 continued....

CARES (MED.INT.)4	-0.01	-0.29	0.08	-0.05	-0.08	***0.91***	-0.03	-0.01	-0.05
CARES (SEXUAL) 4	***0.91***	0.10	0.06	-0.04	-0.01	-0.10	-0.01	-0.02	0.24
CARES GLOBAL 4	***0.68***	***0.65***	0.17	0.04	0.01	0.21	0.02	0.02	-0.12
RSCL (PSYCH) 4	0.33	***0.89***	0.05	0.09	-0.05	0.05	0.11	-0.01	-0.08
RSCL (GI) 4	0.36	***0.61***	0.18	0.07	0.03	0.49	0.23	0.09	-0.16
RSCL (SENSORY)4	0.12	0.11	0.05	***0.95***	-0.01	-0.05	0.02	0.13	0.02
RSCL (FATIGUE)4	0.29	***0.69***	0.11	0.26	0.04	0.13	0.31	-0.15	0.35
RSCL (MISCELL) 4	***0.74***	0.35	0.24	0.27	0.12	0.05	0.19	0.17	-0.11
ERSS 4	***0.77***	***0.54***	0.02	0.23	-0.02	-0.04	-0.01	0.11	-0.04
HAD(ANX) 8	0.15	***0.92***	0.14	0.05	0.09	0.17	-0.01	0.02	0.09
HAD(DEP)8	0.36	***0.76***	0.19	-0.01	-0.04	0.23	-0.03	-0.09	0.21
CARES (PHYS)8	***0.69***	***0.54***	0.05	0.08	0.01	0.33	0.18	-0.09	-0.11
CARES (PSYCHO) 8	0.48	***0.74***	0.29	0.04	-0.05	0.23	-0.01	-0.04	-0.01
CARES (MED.INT.)8	-0.01	0.29	0.08	-0.05	-0.07	***0.91***	-0.03	-0.01	0.05
CARES (SEXUAL) 8	***0.91***	0.10	0.06	-0.04	-0.01	-0.10	-0.01	-0.2	0.24
CARES GLOBAL 8	***0.66***	***0.66***	0.17	0.02	-0.04	0.23	0.03	-0.01	-0.06
RSCL (PSYCH) 8	0.33	***0.90***	0.06	0.07	-0.08	0.09	0.07	-0.02	0.01
RSCL (GI) 8	0.34	***0.62***	0.19	0.05	-0.05	0.41	0.22	0.05	-0.10
RSCL (SENSORY)8	0.10	0.12	0.05	0.94	0.05	-0.02	0.04	0.18	0.03
RSCL (FATIGUE) 8	0.28	***0.70***	0.11	0.27	0.07	0.14	0.32	-0.12	0.36
RSCL (MISCELL) 8	***0.71***	0.35	0.24	0.28	0.12	0.04	0.19	0.17	-0.11
ERSS 8	***0.56***	***0.51***	0.32	0.10	0.06	-0.07	-0.09	0.29	-0.16
VARIABLE	**Factor1**	**Factor2**	**Factor3**	**Factor 4**	**Factor5**	**Factor6**	**Factor7**	**Factor 8**	**Factor9**

(significant figures emboldened and italicised)

The criterion for significance of the factor loading in Table 79 was those variables with a loading of >0.5 [Child, 1990]. The factor analysis of these variables have produced nine factors which account for almost 89 per cent of the total variance. An examination of the rotated factor matrix shows the factor loadings. Variables loading most highly on factor one are the CARES physical, sexual and global score at Interview 4, the RSCL miscellaneous symptom score at Interview 4, the ERSS total score at Interview 4, the CARES physical, sexual and global score at Interview 8, the RSCL miscellaneous symptoms score at Interview 8 and the ERSS total score at Interview 8. This factor would seem to represent a measure of physical rehabilitation status.

The variables loading most highly on factor two are numerous: from Interview 1 the HAD anxiety and depression scores, and the RSCL psychological score; from Interview 4 the HAD anxiety and depression scores; the CARES psychosocial score and global score, the RSCL psychological score, gastrointestinal score and fatigue and the ERSS total score; and from Interview 8 the HAD anxiety and depression scores, the CARES physical, psychosocial and global scores, the RSCL psychological, gastrointestinal, fatigue scores and the ERSS total score. Factor two would therefore appear to represent a measure of psychological distress.

The variables loading most highly on factor three are the CARES physical, psychosocial, medical interaction and global score and the ERSS score from Interview 1. Factor three would therefore appear to represent a measure of rehabilitation status at the outset of the study.

There is only one variable which loads on factor four and this is the RSCL sensory score at Interview 4. Factor four would therefore appear to represent a measure of sensory symptoms.

Factor five represents a measure of demographic details because the two variables which load on it are the patient's age and the number of children.

Two variables load on factor six and these are the CARES medical interaction scores at Interview 4 and 8. The medical interaction score on the CARES represents difficulties relating to the medical staff and one

possible interpretation of this factor is that it represents medical interaction problem

Factor seven represents a unique factor because the only variable which loads on it is social class. This factor would therefore appear to represent social class.

Two variables load on factor eight and these are the RSCL sensory and miscellaneous symptoms score at Interview 1. This factor would appear to represent physical symptomatology.

Only one factor loads on factor nine and this is the RSCL fatigue score at Interview 1 and therefore this factor would appear to represent physical fatigue.

These nine factors represent a considerable degree of reduction of redundancy in explaining almost 89 per cent of the variance of the data from an initially large pool of variables (Tables 80 and 81).

Table 80

Factors derived from the rotated factor matrix and the variance explained by each factor.

FACTOR NAME	VARIANCE EXPLAINED (%)
1. PHYSICAL REHABILITATION STATUS	46.20
2. PSYCHOLOGICAL DISTRESS	9.30
3. REHABILITATION STATUS AT OUTSET	8.80
4. SENSORY SYMPTOMATOLOGY	5.90
5. DEMOGRAPHIC DETAILS	5.20
6. MEDICAL INTERACTION	4.70
7. PATIENT'S SOCIAL CLASS	3.40
8. SYMPTOMATOLOGY AT OUTSET	2.90
9. PHYSICAL FATIGUE	2.40

Table 81

Factor eigenvalue, percentage of variance explained by each factor and the cumulative variance for the rotated factor matrix.

FACTOR	EIGENVALUE	% OF VARIANCE	CUMULATIVE VARIANCE (%)
1	19.39	46.20	46.20
2	3.90	9.30	55.50
3	3.71	8.80	64.30
4	2.48	5.90	70.20
5	2.19	5.20	75.40
6	1.97	4.70	80.10
7	1.43	3.40	83.50
8	1.23	2.90	86.40
9	1.02	2.40	88.80

The pattern emerging from this analysis is more or less unambiguously concerned with relevant elements in the experience of the disease and treatment. The content of the first factor (physical rehabilitation status) is the clearest, and that of the other eight factors (i.e. psychological distress, rehabilitation status at outset, sensory symptomatology, demographic details, medical interaction, patient's social class, symptomatology at outset, and physical fatigue) cumulatively accounts 43 per cent of the variance. The factor analysis of the data from the descriptive study appears to demonstrate that the rehabilitation needs of patients with metastatic breast cancer can be distinguished empirically.

Summary of Results from the Descriptive Study

The Study

A sample of 80 patients with metastatic breast cancer were assessed every eight weeks using a variety of measures.

The Sample Size

The sample decreased in number from 80 to 36 over the course of eight interviews due to patients dying from their disease.

Characteristics of the Total Sample

The mean age of the women in the descriptive study was 53.8 years and the majority of women belonged to social class 3 (skilled) according to the OPCS classification.

The majority of patients were married and had two children who were older than 18 years of age and who were no longer living at home with the patient.

The majority of patients had been diagnosed to have breast cancer between one and five years before the diagnosis of metastatic breast cancer, and the majority had originally received a combination of surgery and radiotherapy as first line treatment of breast cancer.

The majority of women had bony metastases and received hormone therapy as treatment.

Characteristics of patients who survived throughout the course of the study

Thirty-six patients survived throughout the course of the study.

The mean age of women who survived was 59.3 years and the majority of women belonged to social class 3 (skilled) according to the OPCS classification.

The majority of patients who survived were married and had two children who were older than 18 years of age and who were no longer living at home with the patient.

The majority of patients who survived had been diagnosed to have breast cancer between one and five years before the diagnosis of metastatic breast cancer, and the majority had originally received a combination of surgery and radiotherapy as first line treatment of breast cancer.

Characteristics of patients who died during the course of the study

Forty four patients died during the course of the study.

The mean age of women who died was 49.2 years and the majority of women belonged to social class 3 (skilled) according to the OPCS classification.

The majority of patients were married and had two children who were older than 18 years of age and who were no longer living at home with the patient.

The majority of patients had been diagnosed to have breast cancer between one and five years before the diagnosis of metastatic breast cancer, and the majority had originally received a combination of surgery and radiotherapy as first line treatment of breast cancer.

Comparisons of the characteristics of the sub-samples

The ages of patients who died and those who survived differed significantly. The results suggest that the survivors were older than those patients who died during the course of the study.

There were no statistically significant differences between the patients who died during the study and those who survived in terms of marital status and social class.

Significant differences were found between those patients who died and those who survived in terms of medical treatment. The results suggest that significantly more patients who survived were receiving hormone therapy compared to those who died.

Medical professional contact

Contact with members of the medical profession both in the community and the hospital was monitored throughout the duration of the study. General practitioner and hospital doctor was consistently high. However, contact with other members of the multidisciplinary team was consistently low throughout the study. The contact remained low despite the prevalence of physical, psychological or social problems.

Mood in the "total" sample

There were no statistically significant differences in mean anxiety and depression scores as measured by the Hospital Anxiety and Depression (HAD) scale across the eight interviews (mean HAD anxiety and depression was approximately 7).

A large proportion of patients (38.8 per cent) scored above the cut off level for possible "case" anxiety on the HAD at the first interview. However, during the course of the eight interviews, this proportion scoring in the possible "case " range for anxiety had reduced, with 16.7 per cent of patients scoring in this range at the eighth interview.

A large proportion of patients (31.3 per cent) scored above the cut off level for possible "case" depression on the HAD at the first interview. However, during the course of the eight interviews, this proportion scoring in the possible "case " range for depression had reduced, with 16.7 per cent of patients scoring in this range at the eighth interview.

Mood in those patients who died and those who survived

The mean HAD anxiety score of patients who survived throughout the course of the study (mean HAD anxiety was approximately 6) had lower mean anxiety scores throughout the course of the study compared with the mean scores of the "total" sample of patients.

The mean HAD depression score of patients who survived throughout the course of the study (mean HAD depression was approximately 6) had lower mean depression scores throughout the course of the study compared with the mean scores of the "total" sample of patients.

Fewer of the "survivors" compared with the total sample scored in the "probable case" range for anxiety on the HAD using the cut-off scores suggested by the authors (range:17 per cent to 25 per cent).

Fewer of the "survivors" compared with the total sample scored in the "probable case" range for depression on the HAD using the cut-off scores suggested by the authors (range:14 per cent to 22 per cent).

The mean HAD anxiety score for those patients who died during the course of the study was high (10.5) at the last interview before death.

The mean HAD depression score for those patients who died during the course of the study was high (10) at the last interview before death.

The proportion of patients who fell into the "probable case" range for anxiety and depression was high (anxiety- 66 per cent; depression 50 per cent).

Comparisons of mood in those patients who died and those who survived during the course of the study

Comparisons of the HAD anxiety data from patients who died during the course of the study and those patients who survived demonstrated a statistically significant difference suggesting that those patients who died during the course of the study had higher levels of anxiety at the last interview before death than the "survivors" at the eighth interview.

Comparisons of the HAD depression data from patients who died during the course of the study and those patients who survived demonstrated a statistically significant difference suggesting that those patients who died during the course of the study had higher levels of depression at the last interview before death than the "survivors" at the eighth interview.

Symptomatology

The mean Rotterdam Symptom Checklist (RSCL) scores of patients with metastatic breast cancer suggest that they had significant levels of psychological, gastro-intestinal, sensory, fatigue and miscellaneous symptoms.

The mean scores on the RSCL scores of patients who survived throughout the descriptive study were slightly lower than the mean scores of the total group of patients.

The mean scores on the RSCL scores of patients who died during the course of the study were slightly higher than the mean scores of the total group of patients.

Rehabilitation status

The mean Cancer Rehabilitation Evaluation System (CARES) global and subscale (physical, psychosocial, medical interaction, sexual and marital) scores suggest that patients rehabilitation status is adversely affected by their metastatic disease.

The mean Edinburgh Rehabilitation Status Scale (ERSS) total and subscale (support, inactivity, isolation, and effect of symptoms on lifestyle) scores suggest that patients are disabled by their metastatic disease.

Rehabilitation status in those patients who died during the course of the study and those who survived

The mean scores on the CARES global scores of patients who survived throughout the descriptive study were slightly lower than the mean scores of the total group of patients.

The mean scores on the CARES global scores of patients who died during the course of the study were slightly higher than the mean scores of the total group of patients.

The comparison of the data of the global CARES score from the two groups demonstrated a significant difference suggesting that those patients who died during the course of the study had significantly higher CARES global scores than those patients who survived throughout the course of the descriptive study.

The mean scores on the ERSS total scores of patients who survived throughout the descriptive study were slightly lower than the mean scores of the total group of patients.

The mean scores on the ERSS total scores of patients who died during the course of the study were slightly higher than the mean scores of the total group of patients.

The comparison of the data of the ERSS total score from the two groups demonstrated a significant difference suggesting that those patients who died during the course of the study had significantly higher ERSS total scores than those patients who survived throughout the course of the descriptive study.

Contribution of factors to rehabilitation status

No significant associations were found between demographic variables (age, marital status, social class, number of children) and rehabilitation status as measured by the CARES global score and the ERSS total score.

No significant associations were found between rehabilitation status (measured by the CARES global score and the ERSS total score) and a range of disease and treatment variables.

Significant relationships were found between mood (measured by the HAD) and rehabilitation status.

Significant relationships were found between symptomatology (measured by the RSCL) and rehabilitation status.

Using stepwise multiple regression analysis, the variance of the CARES global scores was examined, identifying mood, patient's symptomatology, and age of the patient as contributing significantly to it.

Using stepwise multiple regression analyis, the variance of the ERSS total scores was examined, identifying mood, patient's symptomatology, age and the CARES physical and marital domain scores as contributing significantly to it.

The data from Interviews 1, 4 and 8 were reduced successfully using factor analysis. The factor analysis reduced the data to nine factors accounting for almost 89 per cent of the variance. The factor analysis suggests some interesting interrelationships between the variables. The first factor, physical rehabilitation status, accounted for 46 per cent of the total variance.

Chapter Seven

RESULTS

The Pilot Intervention Study

Introduction

This small pilot intervention study was carried out after collection of the data of the main descriptive study. Nineteen patients were approached and, as two patients refused to participate, 17 patients were recruited to the pilot intervention study. Patients were randomised to either the intervention group (n=10) or the "control" group (n=7). Patients in both groups were interviewed every eight weeks and patients were interviewed four times over the course of six to eight months. The fourth and final interview was conducted by a research assistant in order to introduce externally validate the study.

CHARACTERISTICS OF THE SAMPLES

Age

The ages of the two groups of patients are shown in Table 82.

Table 82

Age of patients in the intervention study by group: means, ranges, standard deviation, U value and significance.

INTERVENTION GROUP (n=10)			CONTROL GROUP (n=7)			COMPARISON	
mean	range	s.d.	mean	range	s.d.	U	p
54.70	37-72	11.14	55.71	45-64	11.03	29.50	0.59

There was no statistically significant difference in terms of the age of patients in the two groups using the Mann-Whitney U test.

Social Class

The social class distribution of the two groups of patients is shown in Table 83.

Table 83

Distribution of patient's social class in the pilot intervention study by group

SOCIAL CLASS		Intervention Group (n=10)	Control Group (n=7)
1	Professional	1	1
2	Intermediate	4	2
3	Skilled	3	2
4	Semi-skilled	0	2
5	Unskilled	2	0
Total		10	7

The social class of the two groups, which was coded according to the Office of Population, Consenses and Surveys [1980] classification of occupations, did not achieve a statistically significant difference using a chi square test ($X^2 = 4.48$; df= 4; N.S.).

Marital Status

The marital status distribution of the two groups of patients is shown in Table 84.

Table 84

Distribution of patient's marital status by group

MARITAL STATUS	Intervention Group (n=10)	Control Group (n=7)
Married	8	5
Separated/Divorced	2	0
Widowed	0	1
Single	0	1
Total	10	7

The majority of patients in both groups were married, with only a very small number being single, separated or divorced, or widowed. There was no statistically significant difference in terms of marital status between the two groups ($X^2 = 4.29$; df= 2; N.S.). In addition, only one patient in each group lived alone.

The number, age and number of children living at home of the patient

The interview schedule gathered information regarding the number of children the patient had, their age and the number living at home with the patient (Tables 85, 86, and 87).

Table 85

The distribution of patient's number of children by group

NUMBER OF CHILDREN	Intervention Group (n=10)	Control Group (n=7)
None	3	0
One child	1	1
Two children	6	4
Three children	0	1
Four children	0	1
Total	10	7

There was no statistically significant difference in terms of the distribution of the patient's number of children between the two groups ($X^2 = 5.02$; df= 4; N.S.).

Table 86

The distribution of patient's youngest child's age by group

AGE OF THE YOUNGEST CHILD	Intervention Group (n=10)	Control Group (n=7)
Not applicable	3	0
< 5 years old	1	0
5 - 10 years	1	2
10 - 18 years	0	0
> 18 years	5	5
Total	10	7

There was no statistically significant difference in terms of the distribution of the patient's youngest child's age between the two groups ($X^2 = 1.33$; df= 2; N.S.).

Table 87

The distribution of patient's number of children living at home by group

NUMBER OF CHILDREN LIVING AT HOME	Intervention Group n=10)	Control Group (n=7)
None	7	5
One child	3	1
Two children	0	0
Three children	0	0
Four children	0	1
Total	10	7

There was no statistically significant difference in terms of the distribution of the number of children patients had staying with them at home between the two groups ($X^2 = 4.29$; df= 3; N.S.).

Time since initial diagnosis of breast cancer

The time since the initial diagnosis of breast cancer was categorised into one of four categories: under three months; between three months and one year; between one year and five years; and over five year (Table 88).

Table 88

The distribution of patient's length of time since initial diagnosis of breast cancer by group

TIME SINCE INITAL DIAGNOSIS	Intervention Group (n=10)	Control Group (n=7)
< 3 months	3	0
3 months - 1 year	1	0
1 - 5 years	4	4
> 5 years	2	3
Total	10	7

There was no statistically significant difference in terms of length of time since initial diagnosis between the two groups ($X^2 = 3.79$; df= 3; N.S.). The majority of patients in each group had been diagnosed between one and five years previously. Those patients who had been diagnosed in the previous three months newly presented with metastatic breast cancer

Original treatment for primary breast cancer

The first line treatment patients received at initial diagnosis was categorised into surgery alone; surgery and radiotherapy; surgery, radiotherapy and chemotherapy; and no treatment (no patients in the two samples had surgery and adjuvant chemotherapy alone, hormone therapy alone, or chemotherapy alone as primary treatment therefore these do not appear) (Table 89).

Table 89

Distribution of patient's treatment at initial presentation by group

INITIAL TREATMENT AT FIRST PRESENTATION	Intervention Group (n=10)	Control Group (n=7)
None	3	0
Surgery alone	1	0
Surgery and radiotherapy	5	5
Surgery, chemotherapy and radiotherapy	1	2
Total	10	7

There was no statistically significant difference in terms of initial treatment at first presentation ($X^2= 3.92$; df= 3; N.S.). The majority of patients in both groups had previously had surgery and radiotherapy as treatment at first presentation of breast cancer.

Site of metastatic spread

The site of metastatic spread was categorised into one of four categories for the purpose of the intervention study: bone; lung; liver; and brain (Table 90).

Table 90

The distribution of patient's site of metastatic spread by group

SITE OF METASTASES	Intervention Group (n=10)	Control Group (n=7)
Bone	5	2
Lung	4	3
Liver	0	2
Brain	1	0
Total	10	7

The majority of patients in the intervention group had bone metastases, whereas in the control group the majority had lung metastases. However, there was no statistically significant difference in terms of metastatic spread between the two groups ($X^2 = 4.02$; df= 3; N.S.).

Patient's medical treatment

Patient's medical treatment for metastatic breast cancer was categorised into one of three categories: hormone therapy; chemotherapy; and radiotherapy (Table 91).

Table 91

The distribution of patient's current treatment by group

TREATMENT	Intervention Group (n=10)	Control Group (n=7)
Hormone	4	3
Chemotherapy	5	4
Radiotherapy	1	0
Total	10	7

The majority of patients in both groups were receiving chemotherapy. There was no statistically significant difference in terms of current treatment between the two groups ($X^2 = 0.75$; df= 2; N.S.).

Size of Samples at Each Interview

Patients died during the course of study. One patient died in the intervention group thereby reducing the size of the sample from ten to nine. Two patients died in the control group, reducing the sample from seven to five. The number of patients in each group at Interviews 1-4 is shown in Table 92.

Table 92

Sample sizes at each interview in the intervention group and the "control" group

Interview	Intervention Group	Control Group
1	10	7
2	10	6
3	10	5
4	9	5

Medical professional contact

Patients in both the intervention group and "control" group were asked at each interview to list the members of the multiprofessional team they had seen in the previous months. Tables 93 and 94 list the per centages of patients who had seen the particular member of the team in the month before each interview.

Table 93

Medical professional contact during the month before each interview (per centages shown of those patients who had seen the relevant member of the multidisciplinary team): intervention group

INTERVIEW	1 %	2 %	3 %	4 %
hospital doctor	100	40	70	80
general practitioner	90	60	90	80
psychologist/ psychiatrist	0	40	30	30
nurse counsellor	30	20	30	40
district nurse/ health visitor	10	50	40	40
social worker	10	10	20	10
physiotherapist	10	0	40	40
occupational therapist	10	20	20	20

Table 94

Medical professional contact during the month before each interview (per centages shown of those patients who had seen the relevant member of the multidisciplinary team): "control" group

INTERVIEW	1 %	2 %	3 %	4 %
hospital doctor	100	17	80	100
general practitioner	100	50	80	80
psychologist/ psychiatrist	0	0	0	0
nurse counsellor	57	33	20	25
district nurse/ health visitor	0	0	0	0
social worker	0	0	0	0
physiotherapist	0	0	20	25
occupational therapist	0	0	20	25

The results from each group concerning the contact with members of the multidisciplinary team were subjected to chi square tests to ascertain any differences between the two groups. There were no statistically significant differences between the two groups in terms of contact with the following members of the multidisciplinary team: hospital doctor; general practitioner; psychologist/ psychiatrist; nurse counsellor; social worker; occupational therapist; and physiotherapist. The only comparison which achieved statistical significance was contact with the district nurse or health visitor at interview 2 ($X^2 = 4.36$; $df = 1$; $p < 0.05$).

Type of intervention carried out by the rehabilitation co-ordinator

The type of intervention carried out by the rehabilitation co-ordinator with patients in the intervention group was categorised into one of six categories: counselling and information giving; initiating contact with

psychiatrists/ clinical psychologists; initiating contact with physiotherapists; initiating contact with occupational therapists; initiating contact with social workers; and other intervention (which consisted of supplying forms for disabled parking permits, Mobility Allowance, Attendance Allowance etc.) (see Table 95).

Table 95

Type of intervention carried out by the rehabilitation co-ordinator (total percentage of referrals after each interview)

INTERVIEW	1 %	2 %	3 %	4 %
counselling/ information	100	100	100	100
psychologist/ psychiatrist	30	10	0	0
social worker	10	20	10	10
physiotherapist	0	30	10	10
occupational therapist	10	10	10	10
other	0	0	20	25

RESULTS OF THE STANDARDISED QUESTIONNAIRES IN THE PILOT INTERVENTION STUDY

Hospital Anxiety and Depression Scale HAD)

Patients in both groups completed the HAD at each interview. The mean anxiety and depression scores of the HAD, standard deviations, and results of the Mann-Whitney U test are shown in Tables 96 and 97.

Table 96

HAD (Anxiety) scores in both groups of patients: means, standard deviations, and Mann-Whitney U values.

HAD ANXIETY	Intervention Group		Control Group		Comparison	
AT EACH INTERVIEW	MEAN	S.D.	MEAN	S.D.	U	p
1	7.30	4.52	7.57	5.09	34.5	0.96
2	7.40	4.81	4.83	4.87	20.50	0.30
3	6.40	5.01	5.20	3.70	22.50	0.75
4	7.44	4.77	5.50	3.32	15.00	0.48

Table 97

HAD (Depression) scores in both groups of patients: means, standard deviations, and Mann-Whitney U values.

HAD DEPRESSION	Intervention Group		Control Group		Comparison	
AT EACH INTERVIEW	MEAN	S.D.	MEAN	S.D.	U	p
1	6.40	3.75	7.71	3.15	27.50	0.46
2	6.60	3.66	5.67	3.88	25.50	0.63
3	6.70	4.99	7.00	4.85	22.00	0.71
4	7.44	4.64	6.00	5.72	15.00	0.47

No statistically significant differences are seen between the anxiety and depression as measured by the HAD in either the intervention group or the control group using the Mann Whitney U test.

Using the cut off scores suggested by the authors [Zigmond and Snaith, 1983], Tables 98 and 99 below show the numbers and per centages of patients in both the intervention and "control" group (respectively) who fall in the normal, borderline and case ranges on the anxiety and depression subscales of the HAD.

Table 98

HAD Anxiety and Depression Scores Using the Cut-Off Scores:

Intervention Group

	HAD Score	Anxiety		Depression	
		n	(%)	n	(%)
HAD 1	0-7 (normal)	5	50	6	60
n=10	8-10 (borderline)	2	20	3	30
	11-21 ("case" level)	3	30	1	10
HAD 2	0-7 (normal)	5	50	5	50
n=10	8-10 (borderline)	3	30	5	50
	11-21 ("case" level)	2	20	0	0
HAD 3	0-7 (normal)	7	70	6	60
n=10	8-10 (borderline)	1	10	1	10
	11-21 ("case" level)	2	20	3	30
HAD 4	0-7 (normal)	4	44.4	4	44.4
n=9	8-10 (borderline)	2	22.2	3	33.3
	11-21 ("case" level)	3	33.3	2	22.2

Table 99

HAD Anxiety and Depression Scores Using the Cut-Off Scores:

"Control" Group

	HAD Score	Anxiety		Depression	
		n	(%)	n	(%)
HAD 1	0-7 (normal)	4	42.85	3	42.86
n=7	8-10 (borderline)	1	14.30	2	28.57
	11-21 ("case" level)	3	42.85	2	28.57
HAD 2	0-7 (normal)	4	66.67	4	66.67
n=6	8-10 (borderline)	1	16.67	1	16.67
	11-21 ("case" level)	1	16.67	1	16.67
HAD 3	0-7 (normal)	4	80.00	3	60.00
n=5	8-10 (borderline)	1	20.00	1	20.00
	11-21 ("case" level)	0	0.00	1	20.00
HAD 4	0-7 (normal)	2	50.00	3	75.00
n=5	8-10 (borderline)	2	50.00	0	0.00
	11-21 ("case" level)	0	0.00	1	25.00

The Rotterdam Symptom Checklist (RSCL)

Patients in both groups completed the RSCL. The means and standard deviations for each domain of the RSCL are presented in Tables 100 - 104. These also show the results of Mann-Whitney U tests on the data.

Table 100

RSCL Psychological Domain mean scores, standard deviations, and Mann-Whitney U values.

RSCL Psychological Domain at each interview	Intervention Group		Control Group		Comparison	
	MEAN	S.D.	MEAN	S.D.	U	p
1	8.30	4.94	7.86	6.18	33.50	0.88
2	6.10	4.89	4.67	5.28	22.00	0.38
3	7.40	6.11	6.80	4.55	24.50	0.95
4	8.89	6.53	7.00	4.89	21.00	0.63

Table 101

RSCL Gastro-intestinal domain mean scores, standard deviations, and Mann-Whitney U values.

RSCL Gastro-intestinal Domain at each interview	Intervention Group		Control Group		Comparison	
	MEAN	S.D.	MEAN	S.D.	U	p
1	5.00	4.27	7.45	5.29	25.50	0.35
2	5.50	2.72	5.83	5.35	28.50	0.87
3	4.90	4.07	6.40	4.62	21.50	0.66
4	6.55	4.69	4.00	4.08	12.00	0.25

Table 102

RSCL Sensory Domain mean scores, standard deviations, and Mann-Whitney U values.

RSCL Sensory Domain at each interview	Intervention Group		Control Group		Comparison	
	MEAN	S.D.	MEAN	S.D.	U	p
1	0.80	0.79	0.43	1.13	22.00	0.20
2	0.80	0.92	0.50	1.22	22.50	0.42
3	0.90	0.88	0.40	0.55	17.00	0.32
4	0.89	1.17	0.25	0.50	13.00	0.32

Table 103

RSCL Fatigue Domain mean scores, standard deviations, and Mann-Whitney U values.

RSCL Fatigue Domain at each interview	Intervention Group		Control Group		Comparison	
	MEAN	S.D.	MEAN	S.D.	U	p
1	5.30	2.45	6.14	2.67	29.00	0.56
2	5.60	2.67	4.00	3.52	21.00	0.33
3	5.20	3.22	6.00	3.67	20.50	0.58
4	5.67	3.20	5.00	2.00	19.50	0.94

Table 104

RSCL Miscellaneous Symtpom Domain mean scores, standard deviations, and Mann-Whitney U values.

RSCL Miscellaneous Domain at each interview	Intervention Group		Control Group		Comparison	
	MEAN	S.D.	MEAN	S.D.	U	p
1	5.70	2.79	5.28	4.46	32.00	0.77
2	5.30	3.33	5.17	3.87	27.00	0.75
3	6.70	4.83	5.80	4.08	21.00	0.62
4	7.22	4.23	4.75	3.59	11.5	0.23

Tables 100-104 above indicate that there were no statistically significant differences using Mann-Whitney U tests on the RSCL data.

The Cancer Rehabilitation Evaluation System (CARES)

Patients in both groups completed the CARES at each interview. The means, standard deviations and Mann-Whitney U values of the global and subscale scores of the CARES are shown in Tables 105-110.

Table 105

CARES global scores of each group: means, standard deviations, and Mann-Whitney U values.

CARES Global Score at each interview	Intervention Group		Control Group		Comparison	
	MEAN	S.D.	MEAN	S.D.	U	p
1	0.80	0.45	0.96	0.46	27.00	0.44
2	0.88	0.43	0.94	0.57	28.00	0.82
3	0.95	0.48	0.81	0.47	20.00	0.54
4	1.10	0.59	0.80	0.47	14.00	0.39

Table 106

CARES physical subscale scores of each group: means, standard deviations, and Mann-Whitney U values.

CARES Physical subscale score at each interview	Intervention Group		Control Group		Comparison	
	MEAN	S.D.	MEAN	S.D.	U	p
1	1.19	0.54	1.36	0.61	26.00	0.38
2	1.06	0.55	0.95	0.70	27.00	0.74
3	1.42	0.90	0.69	0.40	11.50	0.10
4	1.68	1.18	1.20	0.78	20.50	0.58

Table 107

CARES psychosocial subscale scores of each group: means, standard deviations, and Mann-Whitney U values.

CARES Psychosocial Score at each interview	Intervention Group		Control Group		Comparison	
	MEAN	S.D.	MEAN	S.D.	U	p
1	0.87	0.56	1.10	0.64	28.50	0.53
2	0.98	0.55	1.04	0.53	29.00	0.91
3	0.97	0.62	0.90	0.56	23.00	0.81
4	1.17	0.72	1.08	0.68	17.50	0.72

Table 108

CARES medical interaction subscale scores of each group: means, standard deviations, and Mann-Whitney U values.

CARES Medical Interaction Score at each interview	Intervention Group		Control Group		Comparison	
	MEAN	S.D.	MEAN	S.D.	U	p
1	0.20	0.26	0.29	0.37	30.00	0.63
2	0.30	0.42	0.08	0.13	22.00	0.38
3	0.20	0.40	0.20	0.45	23.00	0.81
4	0.22	0.32	0.25	0.50	19.00	0.88

Table 109

CARES sexual subscale scores of each group: means, standard deviations, and Mann-Whitney U values.

CARES Sexual Score at each interview	Intervention Group		Control Group		Comparison	
	MEAN	S.D.	MEAN	S.D.	U	p
1	1.63	1.62	1.86	1.68	31.00	0.70
2	1.78	1.52	2.17	2.04	25.50	0.63
3	2.10	1.91	2.00	1.58	24.00	0.90
4	1.56	1.67	1.50	1.29	18.00	0.77

Table 110

CARES marital subscale scores of each group: means, standard deviations, and Mann-Whitney U values.

CARES Marital Score at each interview	Intervention Group		Control Group		Comparison	
	MEAN	S.D.	MEAN	S.D.	U	p
1	0.25	0.41	0.02	0.06	24.50	0.31
2	0.33	0.50	0.00	0.00	18.00	0.19
3	0.42	0.51	0.00	0.00	12.50	0.12
4	0.59	0.87	0.12	0.16	16.00	0.57

The results of the Mann-Whitney U tests on the data from the CARES (global and subscale scores) indicate that no significant differences were found between the two groups of patients.

The Edinburgh Rehabilitation Status Scale (ERSS)

Patients in both groups were assessed using the ERSS. The mean total scores, standard deviations, and the results of the Mann-Whitney U test are presented in Table 111.

Table 111

ERSS total scores of each group: means, standard deviations, and Mann-Whitney U values.

ERSS Total Score at each interview	Intervention Group		Control Group		Comparison	
	MEAN	S.D.	MEAN	S.D.	U	p
1	6.00	3.71	5.29	3.45	34.00	0.92
2	5.90	3.38	4.20	2.77	16.50	0.29
3	7.30	3.71	5.60	3.85	19.00	0.46
4	8.44	5.57	4.75	3.77	9.50	0.19

Using the Mann-Whitney U test on the ERSS total scores of both groups at each interview, no significant differences were found between the two groups. No significant differences were found in the subscales of the ERSS and have not been presented.

Responses of patients in the intervention group to evaluation questionnaire

At the fourth and final interview patients in the intervention group (n=9) were given an evaluation questionnaire to complete by the research assistant.

Responses to the closed questions on the evaluation questionnaire

The patients in the intervention group answered a range of questions concerning their overall impression and satisfaction with the service. The responses to each question are given below in Tables 112- 119.

Table 112

The number of visits and telephone calls patients received from rehabilitation co-ordinator

Response	Number
More than enough	2
Enough	7
Total	9

The majority of patients said that they had received "enough visits" and phone-calls from the rehabilitation co-ordinator (no patients felt that they had received "not enough").

Table 113

The information and advice on problems patients received from rehabilitation co-ordinator

Response	Number
Advice on some problems	2
Advice on all problems	7
Total	9

The majority of patients said that they had received advice on "all problems". No patients said that they had received no advice on their problems.

Table 114

The practical help with the problems patients instigated by rehabilitation co-ordinator

Response	Number
Practical help on all problems	9
Total	9

All the patients said that they had received practical help from the rehabilitation co-ordinator for "all their problems" (no patients said that they had received help with "some of the problems" or " none of the problems").

Table 115

The amount of practical help with problems patients received instigated by rehabilitation co-ordinator

Response	Number
More than enough help	6
Enough help	3
Total	9

The majority of patients said that they had received "more than enough help" (no patients said that they had received "not enough" help).

Table 116

The practical assistance patients received

Response	Number
Very helpful	9
Total	9

All patients said that the practical assistance they received was "very helpful" (no patients said that the practical assistance was "not at all helpful" or "helpful").

Table 117

The length of time taken to provide information or help for patients

Response	Number
Just right	9
Total	9

All the patients said that the length of time taken to provide information or help was "just right" (no patients said that the time taken was "too slow" or "too quick").

Table 118

Satisfaction/ dissatisfaction with the visits received by the patient from the rehabilitation co-ordinator

Response	Number
Very satisfied	9
Total	9

All patients said that they were "very satisfied" with the visits from the rehabilitation co-ordinator (no patients said that they were "dissatisfied" or "satisfied").

Table 119

Perceived difference to patient's life by the visits of the rehabilitation co-ordinator

Response	Number
Made life better	7
Made no difference to life	2
Total	9

The majority of patients said that the visits by the rehabilitation co-ordinator "made life better" (no patients said that "it made life worse").

Answers to open questions on the evaluation questionnaire

The qualitative responses to the open questions were categorised into concerns and issues. A useful definition of these is:

> " a concern is any matter of interest important to one or more parties....The importance of concerns may often be assessed by reference to the number of persons that express them, but a concern expressed be even one individual may, because of that individual's special perspective or degree of insight, be vital. An issue is any statement , proposition or focus that allows for the presentation of different points of view; any proposition about which reasonable persons may disagree, or any point of contention" [Guba and Lincoln, 1981, p 304]

The aspects of the service which patients were most satisfied with

Many patients identified three concerns relating to their satisfaction with the rehabilitation co-ordinator service:

(a) Having someone to talk to/ confide in for all the members of the family.

As one patient said

> "Just to be able to talk freely with someone and who all the family felt at ease with in our own home"

.....and another.....

> "It was good to be able to confide in [the rehabilitation co-ordinator] - somebody who was outwith the family"

It was apparent from observation that patients and their families appreciated the visits at home, giving them some "control". Most patients felt nervous when going to the hospital for clinic appointments or treatment. Frequently patients and members of the family asked about a particular matter which had been raised at a previous clinic appointment.

(b) Regular contact either by telephone calls or visits

Many patients agreed that the regular visits or phone-calls were reassuring.

One patient said

> "You always knew that she would phone regularly and also she gave us her phone number if there was anything we needed to ask about. It was reassuring to know that."

..... and another.....

> "After an appointment at the hospital [the rehabilitation co-ordinator] would phone to see how I got on and if there were any problems. Then she would visit regularly."

(c) Having immediate advice

An aspect which many patients agreed with regarding the rehabilitation co-ordinator service was being able to get "immediate advice".....

> "You knew that when you phoned her that she would try and see to your problem immediately by getting in touch with someone at the hospital or whatever. That was important because it made us feel less anxious."

<u>The aspects of the service which patients were least satisfied with</u>

The only concern identified was that patients did not know what the study would involve.

For example, one patient said

> "I felt unsure when first approached to take part in the study. I really didn't know what to expect."

<u>If the service was offered to other patients in the future, what were the patient's suggestions</u>

Three concerns were identified in answer to this question:

(a) The content of the questionnaires.

Some patients found some of the questions too personal. For example, one patient said

> "There should be less intimate questions in the questionnaires".

(b) The timing of the interviews.

Some patients agreed that the visits should be more frequent. For example, one patient said

"Every month would be great because a lot could have happened in eight weeks."

(c) The availability of the service. Patients agreed that the service should be available to more patients. For example one patient said that

> "It should automatically be offered to other patients."

Summary of the results from the pilot intervention study

The intervention study

A total sample of 17 patients were randomised to either an intervention group (n= 10) or a "control" group (n= 7). Patients in both groups were interviewed at home every eight weeks four times. The fourth and final interview was conducted by a research assistant in order to introduce a measure of independence to the study.

The sizes of the samples

The sample size in both groups decreased during the course of the study due to patients dying from their disease. The size of the intervention group decreased from ten to nine, and the "control" group decreased from seven to five during the course of the study.

Demographic differences between the two groups

There were no statistically significant differences between the two groups in terms of age, marital status, social class, number and age of children.

Differences relating to disease and treatment variables

There were no statistically significant differences between the two groups in terms of the time since initial diagnosis, original first-line treatment, site of metastatic spread, and treatment for metastatic disease.

Differences relating to data from standardised questionnaires

There were no statistically significant differences between the two groups in terms of HAD scores, RSCL scores, CARES scores, and ERSS scores at Interviews 1-4.

Responses of patients in the intervention group to the evaluation questionnaire

The majority of patients in the intervention group were satisfied with the service provided by the rehabilitation co-ordinator. The results suggest that patients received enough visits, advice and practical help on all their problems, the practical assistance they received was very helpful and the length of time taken to provide information or help was just right. The majority of patients said that the visits by the rehabilitation co-ordinator made their life better. The qualitative responses to the open questions suggested patients found the aspects of the service they were most satisfied with related to the ability to talk openly and confide with someone, the regularity of the visits and the phone-calls, and being able to get immediate advice. Patients said that they did not know what to expect from taking part in the study but, if it was offered to other patients in the future, it should be offered automatically, some of the questionnaires should have less intimate questions, and the visits should be more regular.

Chapter Eight

DISCUSSION AND CONCLUSIONS

Introduction

Breast cancer is the most common type of cancer in women. Each year in the U.K. 26,000 women are newly diagnosed with breast cancer and nearly 16,000 die from it [Cancer Research Campaign, 1991]. In recent years there has been increasing interest in the psychological impact of breast cancer and its treatment on women. However, few systematic studies have been carried out describing the rehabilitation needs of these women. Studies monitoring the psychological impact and rehabilitation needs of women with breast cancer have predominantly focused on those women with primary breast cancer: few studies have been carried out monitoring the needs of women with metastatic disease. The studies presented here have described the rehabilitation needs and undertaken a small pilot intervention study to test out a method of resolving the rehabilitation needs in a sample of women with metastatic breast cancer.

This Chapter discusses the results of the descriptive study and pilot intervention study in terms of: the hypotheses tested; previous research studies monitoring rehabilitation needs and psychosocial sequelae of breast cancer and its treatment. The limitations of the main study and pilot intervention study are addressed and recommendations for further study are discussed.

The hypotheses tested in the descriptive study: accepted or rejected?

(1) Patients have rehabilitation needs throughout the course of their metastatic disease:

The results of the descriptive component demonstrate that patients have rehabilitation needs throughout the course of their metastatic disease, therefore Hypothesis One is accepted.

(2) Rehabilitation needs are not detected in the majority of patients with metastatic breast cancer:

The results of the descriptive study support this hypothesis, given the low levels of medical professional contact seen throughout data collection of the main descriptive study. Hypothesis Two is therefore confirmed.

(3) Demographic factors (such as age, marital status, social class) are associated with rehabilitation needs:

No significant associations were found between rehabilitation status as measured by the CARES global score and the ERSS total score and the following demographic details: age, marital status and social class. However, the multiple stepwise regression analysis demonstrated that age did contribute to rehabilitation needs, when analysed in the context of mood status: younger patients with higher HAD scores, demonstrated higher CARES global scores. Hypothesis Three therefore is rejected in terms of marital status and social class, and accepted in terms of age.

(4) There is correlation between physical symptomatology and anxiety and depression in patients:

Strong associations were found between physical symptomatology and anxiety and depression in patients. Hypothesis Four is therefore accepted.

(5) Rehabilitation needs change during the metastatic phase of breast cancer. The mean CARES-SF global scores and mean ERSS total scores do not change significantly across the eight interviews. Therefore Hypothesis Five is rejected.

(6) There are differences in rehabilitation needs of patients receiving different treatments for their metastatic disease:

No associations were found between treatment variables and rehabilitation needs. Hypothesis Six is therefore rejected.

The hypotheses tested in the pilot intervention study: accepted or rejected?

(7) **Patients have rehabilitation needs throughout the course of their metastatic disease:**

The results of the pilot intervention component demonstrate that patients have rehabilitation needs throughout the course of their metastatic disease. Hypothesis Seven is therefore accepted.

(8) **A rehabilitation co-ordinator does improve significantly the detection of rehabilitation needs:**

There were no significant differences in terms of medical professional contact between the two groups. Hypothesis Eight is therefore rejected.

(9) **A rehabilitation co-ordinator does improve significantly referral for treatment of rehabilitation needs:**

There were no significant differences in terms of medical professional contact between the two group. Hypothesis Nine is therefore rejected.

(10) **Patients perceived the services of a rehabilitation co-ordinator to be of benefit during their metastatic disease:**

Patients reported the services of the rehabilitation co-ordinator to be of value to them in many respects. Hypothesis Ten is therefore accepted.

Discussion of the Results of the Descriptive Study in the Context of Previous Research Studies

Rehabilitation needs

Results from the current study show that change in patients' mean CARES-SF global score, medical interaction and marital subscale scores did not change significantly across the eight interviews. However, patients mean physical, psychosocial and sexual subscale score did change significantly across the eight interviews.

In a study by Schag et al [1991] monitoring rehabilitation needs in a sample of primary breast cancer patients using the CARES-SF on three different occasions (one, seven and thirteen months after diagnosis of primary breast cancer) the global CARES-SF score decreased significantly between the first interview and the third interview. This result complied with the prediction of Schag et al that the rehabilitation needs of newly diagnosed breast cancer patients with localised disease would show a decline over the course of the first year after primary surgery. In examining the subscale scores of the CARES-SF, Schag et al found that the mean physical and psychosocial subscale scores showed significant change between all interview points. No mention was made by the authors of the sexual subscale, however, the marital subscale score on the CARES-SF did not show improvement until 13 months after surgery (the final interview). Similar findings were found by Wingate et al [1989] monitoring the rehabilitation needs of a group of women following mastectomy for primary breast cancer.

The findings of the study by Schag et al and Wingate et al, and the present study markedly differ. It is interesting to compare the mean scores at the last interview in the present study and the study by Schag et al The mean CARES-SF global score in the present study was 0.80 and the mean CARES-SF global score in the study by Schag et al was 0.40. This would suggest that the patients in the present study had greater rehabilitation needs than patients with primary breast cancer. This finding is not surprising. More research is needed, however, to monitor patients with metastatic breast cancer in order to understand what is the "normal" level of functioning in this population over time.

Given the overlap between the definitions of "quality of life" and "rehabilitation", comparisons can be made between the findings of quality of life studies and the present study. Similar to the findings of Schag et al [1991], quality of life studies comparing the effect of radical and conserving surgery have found that quality of life improved and the suffering from psychological and physical complaints decreased with time in both groups of patients [de Haes et al, 1986; Schain et al, 1983].

Comparisons of the findings of the present study with the findings of studies monitoring the psychosocial sequelae of diagnosis and treatment of breast cancer or quality of life studies are made difficult due to the fact that many research studies concentrate on a single point in time, often not specified and often not linked to disease-related variables [Freidenbergs, 1981-1982]. These studies predominantly focus on the impact of the disease and its treatment on mood. In addition, they focus on the impact of primary disease and its treatment.

The paucity of literature specifically monitoring the rehabilitation needs of patients with advanced cancer makes comparison of the results of the present study difficult. The same problem exists in interpreting the patients' ERSS scores in the present study. The authors of the ERSS validated its use in non-cancer populations. However, in order to understand the ERSS scores in terms of dysfunction, the authors suggest multiplying the ERSS total score by 3.57 [Affleck et al, 1988]. The mean percentage dysfunction for the patients in the main descriptive study would range from a minimum of 21 per cent to 34 per cent. This does give meaning to the mean ERSS total score and in fact suggests that, on average, patient's level of dysfunction was not severe. Those patients who died during the course of the study demonstrated a higher mean percentage dysfunction at the last interview before death (36 per cent). This result is not surprising given the high levels of symptoms patients were experiencing. This finding is consistent with quality of life studies of terminally ill cancer patients. In a study by Morris and Sherwood [1987] patients tended to undergo serious reductions in life quality prior to the last twelve weeks of life: "cancer patients experience a major loss of quality of life at a period prior to the last 12 weeks of life, followed by another major loss during the last few weeks of life" [Morris and Sherwood, 1987]. This finding of decreased quality of life in most areas of

function during the last few weeks of life was irrespective of where the patient was: at home or an in-patient at hospital or hospice.

The mean subscale scores of the ERSS demonstrated that the "effect of symptoms" subscale consistently was higher than the other mean subscale scores on the ERSS. The mean "isolation" subscale score was consistently the lowest throughout the course of the eight interviews. In attempting to interpret these results the higher mean score obtained on the "effect of symptoms on lifestyle" may be due to the side-effects of treatment. Despite the majority of patients receiving hormone therapy as treatment for their metastatic disease, a considerable number of patients were receiving chemotherapy. The side effects of chemotherapy, such as alopecia, nausea, vomiting, and lethargy are often referred to in the literature. The effect of these side effects on the patient's lifestyle can be profound.

In attempting to interpret the consistently lower mean scores on the "isolation" subscale of the ERSS (which is a social behavioural subscale for involvement in roles and relationships), reference can be made to recent studies monitoring social support of patients with cancer. Cobb [1976] defined social support as information leading individuals to believe they are cared for and loved, esteemed and valued, and belong to a network of communication and mutual obligation. Most researchers agree that social support is a multidimensional construct comprising of informational support (provision of knowledge), tangible support (specific activities which are perceived to be helpful to the individual) and emotional support (someone with whom the individual can confide and share) [Bloom, 1986]. Marital status has frequently been used as an indirect measure of emotional support [Bloom, 1986]. In the present study the majority of patients were married and had children who were on average older than eighteen years of age. It would seem likely, therefore, that patient's close family members "rallied round" when the patient was diagnosed with metastatic disease and therefore the mean score on the "isolation" subscale of the ERSS was low (i.e. adequate involvement in roles and relationships) throughout the study. Northouse [1988] examined the role of social support and mood in patients and their husbands following the wife's mastectomy. Both the patients and their husbands who reported higher levels of social support reported fewer adjustment difficulties immediately after surgery and one month later. There is consistent evidence linking social support with better psychosocial

adjustment to primary breast cancer and its treatment [Woods and Earp, 1978; Bloom et al, 1978; Vachon, 1986]. However such an association has not been described in the area of patients with metastatic breast cancer.

Mood

There was no statistically significant difference in terms of patients mean HAD anxiety and depression scores across the eight interviews. Previous studies of patients with cancer have reported increased distress over time. For example, a longitudinal study by Ell et al [1988; 1989] studied patients with cancer over a two year period. Results demonstrated a pattern of increasing distress over a time. However, another study by Hughes [1985] of patients with lung cancer found that patients mean depression scores decreased over time.

In the present study, comparisons of the mean HAD anxiety and depression scores or the two "sub-groups" (the patients who died during the course of the study and those patients who survived throughout the course of the study) did demonstrate a significant difference. Those patients who died during the course of the study demonstrated significantly higher levels of anxiety and/ or depression at the last interview before death compared with those patients who survived. This finding perhaps can explain the opposing results obtained by Hughes [1985] and Ell et al [1988; 1989]: those patients who are dying from their disease demonstrated higher levels of distress.

The findings in the current study comparing the mean HAD anxiety and depression scores in the patients who died during the course of the illness and those who survived are consistent with the findings of previous studies by Morris et al [1986] and Morris and Sherwood [1987]. Morris stated that "most distressed conditions predominate for only a short time" before death with a sudden decline in quality of life when death is imminent [Morris et al, 1986].

Using the cut-off scores suggested by the authors [Zigmond and Snaith, 1983] the HAD scores can also be used to indicate case levels for anxiety and depression. The data from the main descriptive study suggested that a relatively large proportion of patients scored in the case range for either anxiety and depression at diagnosis of metastatic breast cancer. However,

over the course of the eight interviews the proportion of patients scoring in the case range decreased. One possible explanation of this finding is that patients were very distressed at diagnosis of metastatic breast cancer but with time passing "adapted" to their diagnosis: at diagnosis patients felt "helpless" and "hopeless", but over time " hope" was restored. Several studies have invoked the concept of "coping" to explain the adjustment of patients to cancer [Weisman and Worden 1976-1977; Lloyd et al, 1984; Ell et al, 1989]. Many theoretical models have been described to explain the coping and adjustment reactions to a diagnosis of cancer. Folkman [1984] and Folkman and Lazarus [1980] have described a model of coping in which the patient makes cognitive appraisals of the "threat" of the disease. In the context of diagnosis of metastatic disease the patient would make an appraisal based on "life threat" probably derived from fears of death, physical suffering and deterioration. The theory would predict that this would relate negatively to adjustment and would create a disruption to the patient's equilibrium. This would explain the relatively large proportion of patients scoring in the case range for anxiety and depression on the HAD at diagnosis of metastatic breast cancer. However, following this initial period, secondary appraisal would occur when the patient evaluates their coping resources. This perceived control would then cause levels of anxiety and depression to decrease over time. Despite the mean anxiety and depression scores in the present study demonstrating no significant change over time, the number of patients scoring in the case range for anxiety and depression on the HAD does decrease over time. The perceived control of the situation has been described by Taylor et al [1983] as "mastery over the situation" which in turn leads to a state of reduced distress and increased coping.

A further finding of the current study in terms of mood concerned those patients at the last interview before death: approximately two out of three patients scored in the case range for anxiety and one in two patients scored in the case range for depression. This is an high proportion of patients. At this final interview, patients were experiencing high levels of physical symptomatology and as a result perhaps realised the severity of their situation. In fact research carried out in patients at a similar stage of their illness has described this period as representing "nearness to death" [Cassileth et al 1985].

Raised levels of anxiety and/ or depression have been noted by numerous researchers in cancer patients receiving palliative therapy [Hinton, 1963; Cassileth et al, 1985]. These studies have often taken the view that symptoms such as pain, breathlessness, weight loss and limited functional ability contribute significantly to psychological distress. One could put forward the view that the high levels of distress are a reflection of the perceived loss of control over their life situation. Using the model of coping suggested by Lazarus [1980] and Folkman and Lazarus [1980], one might conclude that patients at this stage in their illness are making an appraisal of the "life threat" facing them, and that if their appraisal is accurate, one would predict a negative effect on adjustment, resulting in high levels of psychological distress. Hence, there is a complex interaction between physical symptoms and negative cognitive appraisal. The multiple stepwise regression analysis from the present study suggests a complex inter-relationship between rehabilitation status, mood and symptomatology. Therefore, attempts to rehabilitate patients with metastatic breast cancer should embrace all these elements in order to be effective.

Few studies have been conducted examining distress in patients with metastatic breast cancer. A recent study by Hopwood et al [1991] examined patients with advanced cancer of the breast (n=122) and she found that 27 per cent of the sample scored in the case range on the HAD on either the anxiety subscale, the depression subscale or both. A further 18 per cent scored in the borderline range on either the anxiety subscale or depression subscale. It is, however, difficult to compare the findings of the study by Hopwood et al [1991] with the present study. Hopwood et al interviewed patients with "advanced breast cancer" but no details are given regarding the length of time since diagnosis of advanced disease. In addition, the definition of "advanced disease" is unclear because the disease could be locally advanced with no distant metastases. Hence, the apparently homogeneous group of patients could indeed be composed of patients at different stages of the disease process. However, an interesting finding of this study was that 13 per cent of patients who scored in the case range on the HAD who were interviewed on a second occasion 1-3 months later, were persistently anxious or depressed. This result is similar to the proportion of patients in the present study who scored in the case range for anxiety and or depression on the HAD at the eighth interview (approximately 17 per cent for anxiety and depression).

Hopwood et al [1991] concluded that "affective disorder may occur in up to one in four patients with advanced cancer of the breast, and be persistent in one third of these". In contrast, the present study suggests that affective disorder may occur in up to one in three patients with metastatic breast cancer and be persistent in a quarter of these.

The results of the present study are comparable to a number of other studies in which self-assessment methods were used. Craig and Abeloff [1974] using a well-known scale (the Symptom Checklist-90) with 30 cancer patients reported depression in 50 per cent and elevated anxiety in 30 per cent. Farber et al [1982] using the same scale found that 40 per cent of cancer patients scored in the "depressed range". The findings of the present study lie within the range of psychological morbidity found by other researchers working in this area, although others have not restricted themselves to a homogeneous sample of cancer patients and have used small numbers which may explain the variability of the results.

The relationship of mood and rehabilitation status

A strong association was found between mood and rehabilitation status in the present study. This finding is not surprising given rehabilitation status embodies psychological function in its definition.

Previous studies have investigated the association between mood and physical function in the early period (up to six months after diagnosis of primary disease). Goldberg et al [1984] found that there a was strong association between depression and the Karnofsky Performance Status at six months after diagnosis of cancer. However, no association had been found at previous interviews at two and four months after diagnosis. Hughes found that there was a highly significant association between the Karnofsky Performance Status and depression, and between the presence of hypercalcaemia at the time of diagnosis. A study by Cella et al [1987] investigated the relationship between a general concept of psychological distress, extent of disease and performance status in a large sample of patients with lung cancer. The study found that there was a statistically significant association between the extent of physical impairment and mood disturbance. There was also an interactive effect with the extent of disease so that the increase in mood disturbance seen in patients who have a more impaired physical status is more pronounced for patients

with extensive disease [Cella et al, 1987]. However, more studies are needed to describe fully the relationship of mood and rehabilitation status in patients with advanced disease.

Symptomatology

Over the course of the eight interviews patients mean RSCL demonstrated significant change in psychological and gastro-intestinal symptoms. The difference was apparent between interviews one and five for gastro-intestinal symptoms (symptomatology being greater at interview five). A possible explanation for this finding is that a number of patients had not commenced treatment at the first interview, but by the fifth interview were experiencing the side-effects of treatment (particularly those patients receiving chemotherapy). Despite the difference in the mean scores of the psychological symptoms being significant, no one pair of interviews could account for the difference.

Other studies using the RSCL have been conducted by de Haes [1987] in patients receiving chemotherapy for ovarian cancer and they were interviewed on one occasion. Comparisons therefore of trends between the present study and the study by de Haes et al are impossible. However, patients in the study by de Haes et al who were receiving chemotherapy experienced tiredness, lack of appetite, worrying, feeling depressed, nervousness, nausea, feeling tense, heartburn, loss of hair and constipation. These symptoms fall almost entirely into the categories of psychological or gastro-intestinal symptoms (with the exception of tiredness and loss of hair). These findings are similar to the symptoms in the present study who were receiving chemotherapy.

Contribution of symptomatology to rehabilitation status

In the present study a strong association was found between symptomatology as measured by the RSCL and rehabilitation status as measured by the CARES and the ERSS.

Other studies have been conducted monitoring the association between symptomatology and psychological status. The definition of rehabilitation encompasses psychological function and therefore the findings of these studies are relevant. Studies have reported a significant association

between physical symptoms and psychological distress in patients with cancer [McCorkle and Quint-Benoliel, 1983; Hughes, 1985; Bukberg et al, 1984; Cella et al, 1987]. Symptomatology, such as pain, breathlessness, weight loss and fatigue which could be regarded as an aspect of physical disability, has been found to raise the prevalence of depression. Hinton [1963], for example, found that 40 per cent of terminally ill cancer patients with pronounced symptoms were depressed in contrast to 20 per cent of patients where symptoms were not a feature. However, other studies have failed to demonstrate such an association [Taylor et al, 1985; Cassileth et al, 1984]. The discrepancies in these findings may be due to the studies monitoring the distress and symptomatology in patients with different types of cancer, or the studies adopted different methodologies or assessment tools.

Detection of rehabilitation needs

In the present study, detection of rehabilitation needs was monitored by the contact patients had with members of the multidisciplinary team. It is clear from the low percentage of patients at each interview who had seen various members of the rehabilitation team that "detection" of problems was poor. This was particularly the case with the "para-medical" professionals (clinical psychologist, physiotherapist, social worker and occupational therapist). The reasons for this can be numerous: patients were being interviewed in their own home and the majority of patients had only brief contact with the hospital, attending for out-patient follow-up clinic appointments or attending for chemotherapy or radiotherapy. Patients were only admitted to hospital as an in-patient when there was a perceived medical "crisis" requiring immediate hospitalisation for treatment purposes. This relatively short contact with hospital staff did not therefore lend itself to the detection and, hence, referral to a member of the multidisciplinary team. In addition, because patients were still living in their own home, rehabilitation strategies, which are a novel idea in the hospital-based oncology department are relatively unheard of in the community, which rely on domiciliary physiotherapy and occupational services, social work departments and general practitioners etc. Irrespective of the problems relating to the detection of rehabilitation needs in the population of metastatic breast cancer patients, education of the members of the multidisciplinary team that rehabilitation of patients

is not only a possibility but necessary if the true potential for patients with cancer is to be realised.

Low detection of rehabilitation needs demonstrated in the present study is in keeping with the findings of previous studies monitoring the detection of rehabilitation needs and psychiatric morbidity in patients with cancer. A major finding of a study by Lehmann et al [1978] was that the main barriers to optimal delivery of rehabilitation care were the lack of identification of patients problems and/ or the lack of referral to available services by physicians unfamiliar with the concepts of rehabilitation. In addition, the stigma of a diagnosis of cancer persists thereby forming a barrier to the implementation of comprehensive rehabilitation and Dietz suggested that:

> "deep seated fear of cancer has, for a long time, prevented widespread public understanding of the potential for cure or long- term survival and rehabilitation."[Dietz, 1980, p 145]

Maguire [1984] in a study of general practitioners who had cancer patients under their care found that they based their work on a central or false assumption. The general practitioners assumed that any patient who developed psychological problems serious enough to warrant help would consult the general practitioner and request treatment. Maguire found in this study that the general practitioners avoided asking direct questions about how the patients were coping with their diagnosis or treatment because they felt that they were not sufficiently up-to-date with the latest knowledge about cancer and its treatment. Goldberg et al [1980] argued that general practitioners failed to recognise psychiatric morbidity as a direct consequence of such attitudes.

Maguire [1985] also found that doctors working in specialist cancer centres who can openly talk about diagnosis, prognosis and treatment find difficulty enquiring how the patient has been adjusting psychologically. Maguire also found that nurses have problems in talking in any depth with cancer patients [Maguire, 1985]. Less than one in four cancer patients who develop psychiatric problems disclose them to anyone involved in their care, perceiving the doctors and nurses too busy to deal with such problems [Comaroff and Maguire, 1981]. Patients believe that if they complain to the doctors about the worries they have about their diagnosis and treatment, the treatment on which their lives depend may be stopped

altogether. Therefore, patients perceived that it was safer not to disclose their worries and concerns [Derogatis et al, 1976]. As a direct result:

> "This low disclosure of problems enables doctors and nurses to maintain the view that few cancer patients develop anxiety, depression or sexual problems" [Maguire, 1985, p821]

However, despite the publication of such papers, the poor detection of psychiatric morbidity and rehabilitation problems in cancer patients remains, as highlighted in the present study. Possible solutions have been suggested to improve detection of psychiatric problems. However, Maguire et al [1980] have argued that it will take a considerable time to alter the priorities of medical and nursing training and ensure that greater attention is given to the learning of essential interviewing skills and assess psychological impact of the illness and its treatment.

The suggestions to improve the detection of psychological problems include training nurses or social workers to monitor patients over time and aid detection and refer patients to an appropriate clinician [Maguire, 1985]. Others have suggested the use of self-assessment questionnaires in the clinical setting to aid detection of mood disorders. Slevin [1992] advocates the use of questionnaires such as the HAD or the RSCL in the clinical setting to aid detection of psychological problems. This suggestion has in fact been adopted by certain researchers and recently Razavi et al [1992] demonstrated that the HAD scale was a specific, simple and inexpensive tool which accurately detected psychiatric disorders in a lymphoma out-patient population. The scale proved to be acceptable to both patients and physicians in the busy clinic situation. Razavi et al conclude that:

> "Future research must seek to look for the feasibility and validity of screening procedures in other site-specific malignancies along with the development of more simple, sensitive and specific methods of detection." [Razavi et al, 1992, p1871]

Another suggestion aims at prevention of psychological problems by offering counselling to patients with cancer. It has been found that counselling need not be prolonged and indefinite and offering an average of six hours is sufficient to relieve anxiety and depression, improving fighting spirit and quality of life [Greer et al, 1992].

In addition to the detection of psychological problems in patients with cancer it is also important to identify physical, social and vocational problems. The literature describes a number of techniques for detection of these latter problems. Fayers et al [1991] describe the use of a daily diary card which was developed by the Medical Research Council to aid the detection of physical problems in patients undergoing treatment for lung cancer. Liang et al [1990] devised a questionnaire to improve the detection of psychosocial needs in cancer patients. Whilst these approaches are currently in their infancy, further research using similar tools is required to assess their efficacy in the area of detection of patient's rehabilitation needs.

Pilot Intervention Study: the results discussed in the context of previous research

The two groups of patients were well matched on a range of demographic variables (marital status, social class, number and age of children) and diagnostic and treatment variables (time since first diagnosis of breast cancer, first line treatment, site of metastases, and treatment for metastatic breast cancer).

This was a small pilot study and was mainly carried out to test out a method of "intervention" by a rehabilitation co-ordinator. It is not surprising that no significant differences were found in this pilot intervention study between the two groups in respect of their rehabilitation status, mood, symptomatology, and contact with members of the multidisciplinary team.

Other studies which have adopted a rehabilitation co-ordinator or "case management" approach have suggested that in order for the service to be effective it should be implemented for at least one year [Chamberlain and Rapp, 1991]. These findings were from studies carried out with non-cancer populations and the application of the concept to oncology in the current study appears to suggest that six to eight months was insufficient to demonstrate significant differences between the two groups in terms of rehabilitation status, symptomatology and mood. There are few outcome studies of case management or rehabilitation co-ordinator service provision and this is true even in areas where the concept has been applied for considerable lengths of time. Preliminary data in the field of

head injury does suggest, however, that it improves the detection of problems in this client group and facilitates referral to appropriate services [McMillan et al, 1992].

The evaluation questionnaire which patients in the intervention group completed at the fourth interview indicated satisfaction with the service. There were no negative comments about the service provided by the rehabilitation co-ordinator. This was an important finding and the reasons for this satisfaction could be many. For example, the inclusion of the patient and their families in the rehabilitation goal-setting perhaps gave them a sense of control or "autonomy" over the situation. In a study by Penman et al [1984] adaptive or maladaptive coping strategies were identified in post-mastectomy patients. Penman and colleagues found that women judged to be coping best after surgery used a greater range of tackling behaviours, exhibiting active engagement with issues raised by diagnosis and surgery. In contrast, poorer copers were characterised by greater use of avoiding and capitulating behaviours, demonstrating more evasion of illness-related issues and a more passive, fatalistic outlook with respect to illness and treatment. In the study by Penman, better copers were less distressed than poorer copers. In the present study this was not demonstrated. Patient satisfaction with service provision has also been associated with the patient feeling "included" in the medical consultation. Inclusion of the patients and their family in rehabilitation goal-setting is in keeping with current decision-making patterns in health care where there is "shared decision making" regarding medical treatment and intervention. In recent years there has been a shift in medical decision-making, where formerly doctors were seen as making all the decisions regarding treatment and care, towards a more egalitarian approach: doctors and patients sharing responsibility regarding these decisions. This has been characterised as a shift away from physician paternalism to patient autonomy [Emanuel and Emanuel, 1992].

Another possible explanation for the patient's satisfaction with the service provided by the rehabilitation co-ordinator relates to her "presence". This could be construed as a type of social support. Using Schaefer's model of social support [Schaefer et al, 1981] which consists of informational, tangible and emotional components, the rehabilitation co-ordinator could be seen to be offering elements of each of these. Informational support refers to the provision of knowledge relevant to the patient's situation, tangible support refers to specific support which is helpful to the patient e.g. provision of forms for Mobility Allowance, and emotional support is the perceived availability of a thoughtful and caring individual (i.e. the rehabilitation co-ordinator) with whom the patient can share their innermost thoughts and feelings. A future research study could test these elements of social support by a randomised control study where there are five "intervention" groups: each group is given either purely informational support, or tangible support, or emotional support, or a combination of all three types of social support, or, finally a control group given no support. The patient's satisfaction with the service could then be compared between the five different groups.

The Descriptive Study Evaluated

The descriptive study used a homogeneous group of cancer patients at a specific stage of their disease and assessed them at regular intervals to monitor their rehabilitation needs using standardised questionnaires which had been found to be reliable and valid. This study attempted to provide new information regarding the problems faced by women with metastatic breast cancer. This study demonstrated that it was possible to monitor the rehabilitation needs in this group throughout the course of their disease. It was a valuable exercise in that it raised the profile of rehabilitation in the field of cancer care and highlighted the plight of these women. It was important in describing problems in the detection of rehabilitation needs and suggests a future role for the education of health care professionals working in this area.

A number of improvements could have been made in the design and method of the study. The size of the sample in the descriptive study reflected the number of patients available within the time restraints of the study. However, more patients should have been accrued to the descriptive study. In addition, the representativeness of the sample may not have been adequate. All the patients were recruited in a consecutive series at Longmore Hospital, Edinburgh which, at that time, was the Regional Centre for the treatment of breast cancer. However, the patients in the present study may not have represented the overall typical picture of patients with metastatic breast cancer.

The descriptive study also made no attempt to control variables beyond those specified. However, the results of the present study demonstrate that two distinct groups of patients emerged: those patients who survived and those patients who died during the course of the study, the younger patients having more aggressive disease than those older patients who develop metastatic breast cancer. It could be argued that a study of patients of a specific age be selected for inclusion in a separate study. Therefore, it would appear that despite every attempt to focus on a homogeneous group of patients with cancer at a specific stage of the their disease, it may not have been sufficiently specific.

The rehabilitation needs of the group of patients in the present study could have been compared with a "control" group of patients, for example following coronary artery bypass surgery. These patients have been shown

to have rehabilitation needs following surgery and may have proved an interesting comparison group.

Bloom and Ross [1982] however, defend not using other patient groups for comparisons and advocate the definition of a clear question to be answered in a specific group of patients with cancer. Their rationale in supporting this argument is that such comparisons introduce a source of bias because between-subject designs are notoriously motivated by a desire to prove:

> "that cancer patients are indeed suffering more .....Researchers working with individuals in the health care system (not only those with cancer) would do well to avoid having to demonstrate that one group of patients is suffering more than another" [Bloom and Ross, 1982, p260].

The choice of the standardised questionnaires in this study could have been improved. The CARES-SF was chosen because it was the only standardised questionnaire available, at that time, which specifically monitored the rehabilitation needs of patients with cancer. However, the selection of the CARES-SF was, in retrospect, a dubious choice as many doubts have been raised by its use. The cost of this questionnaire would be prohibitive in a larger longitudinal study. The rationale for choosing a standardised questionnaire is usually based on the grounds that comparisons with the findings of other studies can be made. Given the cost of this questionnaire, it is doubtful whether it will be used in studies in this country.

The scoring procedure of the CARES-SF, which is set out in the Manual produced by the authors was found to be extremely time-consuming and complicated. Slevin [1992] pointed out that "any questionnaire which is difficult to score will not prove feasible" in a quality of life study of cancer patients. This point is highly relevant to the present study because it is doubtful whether the CARES-SF would be used in a longitudinal study design where there were more than 50 patients, because the time spent scoring the questionnaire would be prohibitive.

The questions in the sexual subscale of the CARES-SF were found by patients in the present study to be too personal. As a result many of the patients did not answer them and therefore when the questionnaires were scored by the researcher, these were rated "zero" indicating that there was

no problem in this area. This may have been misleading because, if the wording had been less personal, patients may have been able to answer freely giving a more accurate picture of their functioning in this subscale. The CARES-SF was developed in the United States where there is perhaps more willingness to discuss sexual matters. It would therefore be helpful to British studies using the CARES to validate its use amongst a British population. In addition, with the application of the CARES-SF in the present study it became apparent that many of the patients did not know how to respond to the problem statement "I find that my clothes do not fit". Patients were asked to respond to this on a scale from "not at all" to "very much". The use of two negatives was confusing: one in the problem statement and another negative in the rating scale. The use of the double negative is a fundamental mistake in questionnaire development [Bennett and Ritchie, 1975].

The Hospital Anxiety and Depression Scale proved to be easy and quick to use by patients in the study. In addition, the scoring system of the HAD was very straightforward. However, it became apparent with use of the HAD that many patients who were fatigued by physical symptoms rated the statement "I feel as if I am slowed down" on the highest category - "nearly all the time" indicating, according to the scoring system suggested by the authors, the presence of depressive symptoms. This issue was raised by Ibbotson et al [1988] but despite this observation, the HAD still produced the best overall performance for screening for psychiatric morbidity in a population of patients with cancer when compared to the General Health Questionnaire and the Rotterdam Symptom Checklist, using the Psychiatric Assessment Schedule as the "gold standard". Hopwood et al [1991] found that the HAD was a useful screening instrument in the detection of psychiatric morbidity but they suggested further research would enable refinements to the cut-off scores thereby improving its sensitivity and sensitivity.

The Rotterdam Symptom Checklist was found to be straightforward to complete by the patients and it was easy to score. One criticism regarding its use was interpreting the scores in terms of normative data. In terms of using the RSCL as a screening instrument to detect psychological or physical symptoms (gastro-intestinal, fatigue, sensory and miscellaneous symptoms) it was difficult to recognise when patients were experiencing abnormally high levels of symptoms as no "cut-off" scores are available.

This has been noted by Watson et al [1992] in a recent large study using the RSCL. They conclude that:

> "many health-related QL assessment methods available for cancer patients provide a numerical rating for specific symptoms. Very few provide guidelines for the clinical interpretation of scores or give any indication to the clinician of what ought to be considered an intolerable and/ or unacceptable side-effect. Where studies involve direct comparisons between different arms of cancer treatment trials this may not be a crucial issue but, for assessment of QL within normal clinical practice, it is often not clear how clinicians can use the data to assist in their clinical decision making and the RSCL is no exception" [Watson et al, 1992, pp 42-43]

In addition, several different versions of the RSCL are available, each having different numbers of items containing different questions. This undermines the validation attempts by the authors because one is not aware which version of the RSCL was validated. It would appear that this scale is still undergoing development as Slevin [1992] points out that the RSCL:

> "does not adequately cover sexual or social dimensions of quality of life and additional physical items have been proposed for use with specific groups of cancer patients" [Slevin, 1992, p 466].

It has to be borne in mind that this type of research is still in its infancy and further developments and refinements will be made to existing standardised questionnaires. It is extremely important therefore to keep abreast of these developments when designing a research study of this nature.

It could be argued that the main study should have utilised measures of locus of control or personality inventories because rehabilitation encompasses the way in which the individual adapts to his/her disability. In defence, the researcher considered using such measures during the planning phase of the study. However, it became apparent that, given the broad definition of rehabilitation, a multimodal approach was necessary adopting a battery of standardised questionnaires to probe adequately each aspect of rehabilitation. The patients in this study were to be interviewed on a regular basis. In addition, a large number of patients were fatigued due to their disease and/ or treatment. Therefore, every attempt had to be made to keep the number of questionnaires to a minimum or risk patient

compliance. As a result, the decision was made to omit measures of personality and locus of control.

The descriptive study attempted to ascertain the detection of rehabilitation needs in a sample of patients with metastatic breast cancer. The operationalisation of "detection" of these problems in the present study may be open to criticism. A connection was made between detection of a particular problem and the contact patients had with members of the multidisciplinary team. For example, if a patient had not been seen by a psychiatrist or clinical psychologist, and on assessment they had scored in the case range for either anxiety or depression on the HAD, the researcher assumed that this problem had not been detected. At the outset of the study, the researcher had investigated many methods of trying to ascertain detection of rehabilitation problems. One possible method was to read the patients medical notes at regular intervals in order to ascertain whether referral had been made to a particular discipline. However, this was flawed because detection of a particular problem could have been made by another member of the multidisciplinary team and this would not have been necessarily recorded in the medical notes. For example, a nurse at the Out-Patient Clinic may have noted that a patient had lymphoedema, and, without telling the patient's Consultant, had contacted the physiotherapist and organised treatment. None of this would have been recorded in the patient's medical notes. The chosen method was therefore, despite its limitations, judged to be the best option available for ascertaining detection of rehabilitation needs.

Respondent fatigue and attrition of patients from the main study was not a problem which is surprising given the nature and stage of patient's disease. The decrease in the number of patients at each interview was due solely to patients dying from their disease. Further analysis was carried out on the data from two different "sub-groups" (those who survived and those who died during the study) affording further valuable information on this total sample of patients.

The Pilot Intervention Study Evaluated

This pilot intervention study attempted to test out a method of improving the detection of rehabilitation problems through the intervention of a rehabilitation co-ordinator interviewing patients with metastatic breast cancer at regular intervals from diagnosis of metastatic disease. This component adopted the same standardised questionnaires as those used in the main descriptive study. Therefore, the criticisms levelled at these questionnaires in the main study also apply to the pilot intervention study.

One obvious criticism regarding the pilot intervention study applies to the extremely small sample size in the "intervention" and "control" groups. At the outset of the study, the intention was to recruit 20 patients: randomising ten patients to each group. However, the time-constraints of the study did not enable the larger quota of patients to be recruited. In addition, even twenty patients would have been a small sample. Ideally, there should have been a larger group of patients in both groups in the intervention study matched in terms of demographic, diagnostic and treatment variables.

Another criticism which is justified, is the short duration of the study: patients being seen on four occasions over a course of six to eight months. The decision to see patients on four occasions for this length of time was due to the time-constraints of the study. Ideally, patients should have been seen for at least a year to determine whether intervention by a rehabilitation co-ordinator had any effect on the rehabilitation needs of patients with metastatic breast cancer. Chamberlain and Rapp [1991] have found that significant differences between intervention groups and controls in case-management studies seem "discernible after a year but not before".

It could be argued that there is a naïve assumption underpinning the effect of a rehabilitation co-ordinator: that intervention could "hold back the tide" of the inevitable sequelae of advanced disease and its treatment. This criticism however, in the author's view is unjustified. It has been shown in the main descriptive study that patients have rehabilitation needs (particularly psychological needs). The question remains whether these needs could be resolved over time through intervention, irrespective of how long the patient has to live. Research suggests for

example that intervention does make a difference to psychological problems [Greer et al, 1992] as well as to physical problems in patients undergoing chemotherapy for testicular cancer [Robinson, 1990].

The essentially quantitative methodology adopted in the pilot intervention study could be criticised because it was perhaps limited in its scope. This criticism could be justified when one looks at the results from the evaluation questionnaire which patients in the intervention group completed at their fourth interview. Despite the results monitoring the rehabilitation needs not demonstrating any statistically significant difference between the two groups of patients (which is not surprising given the small sample), patients in the intervention group were extremely satisfied with the service they received and perceived that the service had improved their life. The more subjective aspects of coping with their disease and treatment were perhaps lost in the plethora of standardised measures monitoring rehabilitation needs. Therefore, the methodology adopted in this pilot intervention study could have adopted a mixed quantitative and qualitative approach: the former tapping variables which the researcher deemed relevant to the patient's rehabilitation; the latter adopting a more global view of the concerns and issues which the patient deemed relevant to her rehabilitation. The two research paradigms, which historically have seemed diametrically opposed, have in recent years been recognised as offering a "way forward" when used in tandem: "both the qualitative and quantitative paradigms have weaknesses which, to a certain extent, are compensated for by the strengths of the others" [Steckler et al, 1992].

The timing of interviews in the intervention study was at eight weekly intervals. A possible criticism was that this not was not sufficiently regular to detect subtle changes in rehabilitation needs. Contact was maintained between the interviews by telephone and enabled the researcher to keep up-to-date with patient's medical management and problems. Although it is not possible to state what is the optimum interval between interviews, future research studies in this area may need to manipulate the interval between interviews in order to assess the most sensitive period to enable the most effective detection of changes of patient's needs.

Difficulty in acting as a rehabilitation co-ordinator both of a personal nature (dealing with the distressing nature of patient's disease) and also of

a professional nature (the researcher's professional background) may have contaminated the data from the pilot intervention study. The researcher's professional background was as a physiotherapist and therefore she may have been more acutely aware of physical needs and therefore be biased in her assessment. of patient's needs. Attempts were made to overcome bias in the latter study by having a research assistant carry out the final interview and administer the evaluation questionnaire to patients in the intervention group. Future studies could adopt a different approach to rehabilitation co-ordination by having a researcher administering the questionnaires and a different person acting as the rehabilitation co-ordinator in order to avoid possible bias.

In addition, problems were encountered by the rehabilitation co-ordinator in referral of patient's to the appropriate services. The underlying assumption of rehabilitation co-ordination is that the services exist. However, in some instances these were not found to be available. For example, clinical psychology services were limited when this study was being carried out. Therefore, if patients were found to have high levels of anxiety and depression, the rehabilitation co-ordinator had to refer the patient for psychiatric intervention and the waiting list for this was lengthy. These types of problems can hinder the effectiveness of the service offered by the rehabilitation co-ordinator and therefore need to be addressed carefully in any study of this nature in the future.

Future Research Directions

The results of the two studies presented here suggest a number of avenues for further research in this area.

The obvious development of the descriptive study into a larger study using a longitudinal design would provide even more detailed and useful information in this area. In addition, such a study could be used as an attempt to replicate the current findings. Such a cross validation study would be essential before embarking on the provision of services based on the current findings. In tandem with this project a larger intervention study would also need to be undertaken with women with metastatic breast cancer and the duration of this study would need to be longer than a year. In this way the efficacy of a rehabilitation co-ordinator could be fully evaluated in this area of cancer care.

The subjects in the present study were being treated in a major cancer centre in Scotland. Future research projects in this area may give greater insights into the impact of breast cancer and its treatment on patients if subjects from district general hospitals were used. Researchers have for some years speculated that the care and attention given to patients treated in specialist cancer centres is quite different to that offered to those in the district general hospital [MacKillop and Johnston, 1986; MacKillop et al, 1988; McIllmurray, 1990]. This question, therefore, needs to be addressed perhaps through the use of a multi-centre trial using both specialist cancer centres and other hospitals.

This study has used women with metastatic breast cancer and therefore the results are only applicable to this group. Future studies must address the rehabilitation needs of patients who have cancer at a different site. The range of different types of cancer is very broad, each having potentially their own specific rehabilitation needs. For example, patients having amputation of a limb for an osteosarcoma will have very different rehabilitation needs to a patient undergoing extensive surgery for cancer of the head and neck, and patients being treated for lung cancer will also have different needs. It has been demonstrated from the findings of the present study that the stage of the disease is important to address when designing a study. The present study identified the needs of women with metastatic breast cancer. Future studies need to identify the needs of men with site-specific cancers (for example, teratoma) and also cancers which affect both men and women (for example, lung cancer which is rapidly increasing in women [Edinburgh Lung Cancer Group, 1987]).

Future investigations should control for the extraneous prognostic variables that may affect adjustment, such as age, different treatments, site of metastases, and time since diagnosis of primary breast cancer. Whilst the present study has provided a useful initial examination of patient's needs with metastatic breast cancer, greater control of the variables would give even more insight.

The present study focused on the rehabilitation needs of the patient. Future studies in this area should include an investigation into the role of the family in rehabilitation of the patient with cancer. Cancer presents, afterall, a dilemma for both the patient and their family and has, in fact, been referred to as "a family disease" with immediate impact of family

functioning, roles, relationships and employment [Cassileth and Hamilton, 1979]. A number of researchers have concluded that the family is important in this area and have noted the dearth of studies including them. As Naysmith et al conclude [1983] "there is surprising little data regarding family interactions while an adult member of the family deals with cancer" (p26). This would be in line with current views that the patient and their family are involved in the goal setting process in rehabilitation [Dudas and Carlson, 1988].

A further research avenue related to the impact of cancer on the family would be to investigate the role of the family in the rehabilitation of the patient with cancer. Such an approach would help the family members as a common finding in the research literature is that families feel impotent and helpless in the patients care [Vachon et al, 1977]. In this latter study for example the carers of cancer patients were compared with the carers of patients with cardiac problems. The carers of the cancer patients felt that there was little they could do to help the cancer patient and as a result experienced significant feelings of anxiety and depression. The carers of cardiac patients, however, felt that they had an essential role to play in providing aid to the patient. This aid was focused on encouraging the patient to make lifestyle changes (diet and taking physical exercise) that they felt would be beneficial to the patients health. These carers were, as a result, significantly less anxious and depressed than those caring for patients with cancer and also they had a greater sense of well being. Helping the carer, therefore, to have a role in the rehabilitation of cancer patients may have a beneficial effect on the carer and as a result merit further investigation.

The results of the present study demonstrated that the detection of rehabilitation problems was poor in the sample of patients. Future research needs to be carried out to test out what can be done to improve the detection of these problems. The problem of detection and methods of improving rates of detection has to do with two areas: that of educating members of the multidisciplinary team what rehabilitation has to offer these patients; and secondly to train members of the team to detect these problems. The former area has links with recent methods of educating general practitioners in palliative care where distance-learning packages have been used to facilitate education in this important area. Similar methods could be employed to educate members of the multidisciplinary

team to improve their knowledge base in cancer care. Such education in rehabilitation oncology would enable these practitioners to focus on the potential available to the patient rather than being pre-occupied with "the cancer" thereby "fostering a positive attitude" to patients with cancer [Watson, 1986]. Training members of the team to detect rehabilitation problems would also facilitate the detection of these problems. Using a similar model to that adopted by Wilkinson et al [1988] a specific member of the team could be trained in the relevant skills, then given the task of monitoring cancer patients over time. Using a randomised controlled trial, the detection rates of rehabilitation problems could be compared to see whether it was effective.

The prevention of rehabilitation problems, in particular the psychosocial problems, also needs to be addressed in future studies. For example, a randomised controlled trial could be carried out whereby patients in the "intervention" arm of the trial were seen on a regular basis in a group for relaxation and gentle exercise, and seen individually for counselling. These patients would be assessed regularly using standardised questionnaires to measure their rehabilitation needs and levels of psychological and physical symptoms. The results would be compared to those from the control group who had received no intervention. A similar approach has been found to be successful in patients following coronary artery bypass surgery in reducing levels of anxiety and depression and rehabilitation needs [O'Rourke et al, 1991]. In addition, "bibliotherapy" techniques could be used in this group of patients whereby patients are given a self-help manual to help them come to terms with their specific disease and its treatment and suggesting positive methods of overcoming any problems. Self-help booklets are widely available for patients with cancer. However, they are usually focused on primary disease and its treatment, and give very general advice on diet etc. A highly specific manual could extend the self-help approach to encompass all the elements of comprehensive rehabilitation. A similar manual has been developed for patients following myocardial infarction and results demonstrated that patients who had had acute myocardial infarction were psychologically less distressed at one year, had significantly less contact with their general practitioners, and significantly fewer were readmitted to hospital in the first six months [Lewin et al, 1992].

Future research in this area will also need to address certain organisational issues in the composition of the research team. Both studies utilised one person to design the study, collect the data and implement the intervention (with the exception of the final interview in the pilot intervention study which was carried out be a research assistant). Over the course of the study this proved to be extremely stressful for that person for a number of reasons. The setting up of the study required the researcher to liaise with a number of different hospital oncology departments with which she was not affiliated. This required a range of negotiating skills as she was viewed with suspicion by these departments and as a result had to gain acceptance by them. Secondly, working with women who had a disease such as metastatic breast cancer imposed a range of stresses and strains. The work was intrinsically linked with suffering as a result of the illness and its treatment and, as was demonstrated in the results, dealing with death became a major issue for the researcher. Finally, the study necessitated a large amount of travelling because the interviews were conducted at the patient's homes which were scattered throughout south-eastern Scotland and this imposed a quite different series of stresses.

Future research, therefore, will need to make appropriate arrangements for providing support to the researcher/researchers working in this area. In addition, the composition of the research team would need to be carefully considered. In the present study, the researcher was female and was working with female patients. The compliance may have been completely different if the researcher in the present study had been male or if in future studies the patient group were to be male, with a female researcher. The areas of the research study that may have suffered particularly, would have been those areas related to sexual functioning as this was found to be a very sensitive area for the women who took part in the current study. In future research studies in this area therefore, careful consideration would need to given to these points.

Future research in this area should aim at a greater understanding of the rehabilitation needs and the role of rehabilitation in cancer care. Emphasis must be focused on ways of improving the detection of these needs, facilitating referral to rehabilitation services, thereby restoring patient's to their optimum level of physical, psychological and social function. As Morris and Sherwood argue, the aim of research in this area should be:

"To increase the success of palliative effort and to decrease dependency, more research and dissemination of knowledge is needed. In particular, we need more data on the ability of clinical interventions to effect quality of life outcomes positively both in the last weeks of life and throughout the treatment process." [Morris and Sherwood, 1987, p552]

Similarly Fallowfield and Clark [1991] make a plea for a greater understanding of the wide ranging effects of breast cancer, they conclude that:

"Meanwhile there is much to be done to help relieve the psychological distress and dysfunction produced by the diagnosis and treatment [of breast cancer]. The experiences of women unfortunate enough to have breast cancer.....show that there is little room for complacency. Many women display quite extraordinary fortitude and courage during the course of their disease; others find that the disease exposes the limitations of their coping repertoires. We could all do very much more to make their burden more tolerable." [Fallowfield and Clark, 1991, p120]

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Appendix A

)THIAN HEALTH BOARD NORTHERN GENERAL, ROYAL VICTORIA AND WESTERN GENERAL UNIT

orthern General Hospital

y Road, Edinburgh EH5 2DQ Telephone 031-332 2525

Your Ref
Our Ref JS/PH MCO/149/89
Date 9.1.90
Enquiries to
Ext. No.

Ms. C.L. Fulton,
Rehabilitation Studies Unit,
Princess Margaret Rose Orthopaedic Hospital,
Edinburgh.

Dear Ms. Fulton,

re: Application MCO/149/89

I write with reference to your recently submitted application to the Ethics of Medical Research Sub-Committee for Medicine and Clinical Oncology entitled "The assessment of need for rehabilitation in patients with metastatic breast cancer".

I now write to inform you that this application was given ethical approval at the last meeting of the Sub-Committee.

Yours sincerely,

Miss J. Smith,
Secretary

INFORMATION FOR PATIENTS

Illness not only causes symptoms but often affects other aspects of people's lives e.g. families, work, independence etc.

I am a researcher undertaking a project to explore the varied physical, psychological and social needs of patients. It is hoped that this study will contribute towards improving patient's care.

If you are in agreement, I would come and see you every eight weeks and ask you to tell me a bit more about yourself as well as the effects of your illness and its treatment. In addition to this, I will ask you to complete several simple short questionnaires concerning how you are feeling. The initial interview would occur at the Longmore Hospital. However, if you give permission, subsequent interviews would most likely take place at your home.

You are under no obligation to take part in this study and you can of course withdraw at at any time. If you do agree to take part we would like you to fill in our questionnaires only for as long as you feel able to.

The information you give will be treated in strictest confidence and will not affect treatment in any way. If I feel that you are expressing worries which may be helped by medical care, I may wish to discuss this with your own doctor. This would only be done however after consultation with you. The information given will be analysed anonymously along with that from other people who have agreed to help us in our study.

Colette L. Fulton

November 1989.

FORM OF CONSENT

I,.....(name) agree to participate in this study. The nature and purpose of the study have been explained to me by Colette Fulton and are acceptable to me.

I understand that I am entering this research of my own free will and am free to withdraw at any time, without necessarily giving any reason. In addition, my participation or non-participation in this project will in no way affect the care that I receive.

Signed..... Date.....

Witnessed by.....

Interview Schedule

Code number:

Physical illness not only causes symptoms but often affects other aspects of people's lives e.g. their interests, their families or their work. For this reason we are asking patients to tell us a bit more than usual about themselves to help us put research on the effects of illness and treatment into the context of people's lives as a whole.

Biographical Data

1. Age .....

2. Marital Status: M/Cohab Sep/Div Wid Single

3. Do you have any children? No Yes

4. If "yes", how many? 1 2 3 4

5. What age is the youngest? 0-5 yrs 6-10 yrs 11-18yrs Older

6. How many children are still living at home?
   1 2 3 4

7. Do you live on your own? No Yes

8. I would now like to ask you some questions about your work.

   What is your occupation.....

   (If Mar/ Cohab) what is your spouse's occupation.....

II Health and illness

9. Until this illness, how has your health been over the years?

Good Fair Poor

10. How long ago were you diagnosed as having cancer of the breast?

Within past six months

Within past year

Between one and five years

More than five years ago

11. What treatment did you have when you were first diagnosed?

Surgery

Surgery and chemotherapy

Surgery, radiotherapy and chemotherapy

Radiotherapy alone

Chemotherapy alone

None

12. What treatment are you currently receiving?

Chemotherapy

Hormone therapy

Radiotherapy

Surgery

None

Combination (specify)

13. Who have you seen in the last month of the following: (give details e.g. how often and for what reason)

a/ General Practitioner

b/ Hospital Doctor

c/ District Nurse/ Health Visitor

d/ Physiotherapist

e/ Occupational Therapist

f/ Social Worker

g/ Nurse Counsellor

h/ Psychiatrist/ Clinical Psychologist

i/ Other (please specify)

From patient's medical notes

Diagnosis: **TNM status:**

Date of initial diagnosis:

Initial Treatment: **Surgery** **Chemo** **XRT** **Comb**

Metastatic Involvement:

Date of diagnosis of metastasis:

Current Treatment: **Surgery** **Chemo** **XRT** **Comb**

Follow-up Interview

1. What treatment are you currently receiving?

Chemotherapy

Hormone therapy

Radiotherapy

Surgery

None

Combination (specify)

2. Have you been to the hospital since I saw you last?

yes no

3. If "yes" what was the reason for the visit?

Chemo Clinic Injection In-patient Other

4. Who have you seen in the last month of the following: (give details e.g. how often and for what reason)

a/ General Practitioner

b/ Hospital Doctor

c/ District Nurse/ Health Visitor

d/ Physiotherapist

e/ Occupational Therapist

f/ Social Worker

g/ Nurse Counsellor

h/ Psychiatrist/ Clinical Psychologist

i/ Other (please specify)

Appendix B

Correlation matrix of variables from interviews 1,4 and 8.

Correlation matrix

	Age	No.child	Soc.Class	Anx 1	Dep 1	Phys 1	Medint 1	Sex 1
Age	1							
No.child	-.315	1						
Soc.Class	-.421	-.138	1					
Anx 1	-.118	-.225	.139	1				
Dep 1	.02	-.191	-.11	.792	1			
Phys 1	.144	-.302	.033	.526	.708	1		
Medint 1	.02	.053	.014	.132	.37	.732	1	
Sex 1	-.398	.293	.297	.037	-.059	.029	.108	1
Global 1	-.232	.011	.058	.519	.504	.468	.404	.441
GI 1	-.053	-.06	-.023	.344	.464	.376	.204	.133
Sens 1	-.188	.094	.165	.098	-.161	-.219	-.105	.349
Fat 1	-.254	.153	.109	.164	.407	.453	.446	.445
Symp 1	.014	-.094	.181	.232	.359	.341	.319	.402
ERSS 1	.137	-.22	-.02	.448	.667	.856	.769	-.008
Psycho 1	-.138	-.056	.151	.508	.57	.658	.584	.122
Psy 1	.165	-.401	.023	.711	.744	.751	.244	.02

Correlation matrix of variables from interviews 1,4 and 8.

Correlation matrix

	Age	No child	Soc.Class	Anx1	Dep1	Phys1	Medint1	Sex1
Anx4	-.181	-.187	.157	.845	.791	.564	.18	-.081
Dep4	-.168	-.125	.069	.609	.673	.656	.335	.021
Psy4	-.305	-.093	.184	.761	.625	.47	.149	.061
GI4	-.19	-.067	.231	.623	.498	.433	.266	.034
Sens4	.044	-.062	.119	.043	.225	.173	.249	.146
Fat4	-.341	-.176	.29	.507	.556	.537	.324	.07
Sympt4	-.266	-.147	.277	.35	.395	.538	.401	.314
Phys4	-.338	-.142	.245	.451	.384	.421	.286	.085
Psycho4	-.24	-.089	.042	.668	.648	.649	.438	.057
Medint4	-.105	.113	0	.326	.341	.178	.211	-.286
Sex4	-.287	.024	.06	.071	.088	.367	.272	.483
Global4	-.313	-.135	.099	.566	.538	.572	.358	.137
ERSS4	-.328	-.115	.101	.424	.438	.446	.192	.313
anx8	-.162	-.164	.104	.801	.797	.603	.203	-.095
dep8	-.225	-.1	.091	.608	.663	.624	.31	.049
psy8	-.32	-.066	.137	.747	.653	.501	.17	.056

Correlation matrix

	Age	No.child	Soc.Class	Anx1	Dep1	Phys1	Medint1	Sex1
GI8	-.236	-.006	.225	.611	.508	.43	.277	.044
Sens8	.07	-.1	.138	08	.253	.191	.227	.127
Fat8	-.323	-.195	.299	522	.569	.544	.313	.062
Sympt8	-.266	-.147	.277	35	.395	.538	.401	.314
Phys8	-.358	-.118	.228	442	.398	429	.292	.085
Psycho8	-.265	-.066	.053	662	.645	.644	.443	.072
Medint8	-.105	.113	0	326	.341	.178	.211	-.286
Sex8	-.287	.024	.06	071	.088	.367	.272	.483
Global8	-.348	-.102	.098	.56	.552	.568	.357	.142
ERSS8	-.291	-.206	.017	.532	.592	.586	.362	.239

Correlation matrix of variables from interviews 1,4 and 8.

Correlation matrix

	Global1	GI1	Sens1	Fat1	Symp1	ERSS1	Psycho1	Psy1
Global1	1							
GI1	.168	1						
Sens1	.168	.297	1					
Fat1	.498	.513	.031	1				
Symp1	.471	.589	.172	.632	1			
ERSS1	.504	.275	-.311	.462	.42	1		
Psycho1	.532	.111	-.386	.391	.445	.776	1	
Psy1	.402	.403	-.065	.328	.409	.598	.566	1

Correlation matrix

	Global1	GI1	Sens1	Fat1	Symp1	ERSS1	Psycho1	Psy1
Anx4	.33	.424	-.131	.202	.15	.43	.487	.575
Dep4	.342	.367	-.221	.34	.031	.468	.389	.49
Psy4	.302	.357	-.125	.198	.062	.331	.444	.413
GI4	.235	.426	-.105	.28	.238	.386	.525	.381
Sens4	.087	.396	.244	.21	.291	.078	-.026	.021
Fat4	.131	.374	-.158	.326	.076	.322	.41	.435
Sympt4	.294	.5	-.003	.265	.299	.381	.39	.327
Phys4	.15	.347	-.119	.11	.028	.293	.369	.195
Psycho4	.32	.461	-.198	.291	.108	.553	.561	.455
Medint4	-.018	.329	-.109	.168	.054	.251	.246	.142
Sex4	.103	.208	-.091	.242	-.016	.176	.173	.086
Global4	.328	.429	-.127	.236	.096	.446	.46	.353
ERSS4	.28	.464	-.048	.219	.127	.276	.271	.248
anx8	.329	.424	-.179	.247	.136	.433	.475	.589
dep8	.34	.313	-.259	.337	.031	.449	.427	.481
psy8	.312	.375	-.168	.247	.067	.346	.457	.435

Correlation matrix of variables from interviews 1,4 and 8.

Correlation matrix

	Global1	GI1	Sens1	Fat1	Symp1	ERSS1	Psycho1	Psy1
GI8	.24	.397	-.144	.316	.217	.384	.548	.367
Sens8	.086	.449	.25	.23	.354	.079	-.008	.082
Fat8	.131	.405	-.149	.337	.114	.321	.415	.462
Sympt8	.294	.5	-.003	.265	.299	.381	.39	.327
Phys8	.151	.347	-.144	.14	.023	.293	.378	.203
Psycho8	.326	.454	-.21	.302	.12	.552	.58	.449
Medint8	-.018	.329	-.109	.168	.054	.251	.246	.142
Sex8	.103	.208	-.091	.242	-.016	.176	.173	.086
Global8	.329	.412	-.155	.268	.088	.439	.473	.353
ERSS8	.509	.51	.007	.336	.327	.565	.459	.421

Correlation matrix

	Anx4	Dep4	Psy4	GI4	Sens4	Fat4	Sympt4	Phys4
Anx4	1							
Dep4	.768	1						
Psy4	.91	.76	1					
GI4	.75	.668	.782	1				
Sens4	.192	.158	.208	.174	1			
Fat4	.744	.701	.741	.625	.32	1		
Sympt4	.528	.601	.591	.599	.383	.579	1	
Phys4	.672	.733	.755	.789	.208	.647	.738	1
Psycho4	.804	.833	.869	.779	.159	.734	.678	.806
Medint4	.383	.512	.271	.569	-.032	.325	.127	.393
Sex4	.214	.447	.381	.335	.126	.381	.584	.613
Global4	.763	.822	.823	.79	.177	.671	.779	.924
ERSS4	.652	.703	.757	.611	.391	.618	.815	.813
anx8	.971	.824	.863	.69	.147	.758	.508	.627
dep8	.763	.981	.762	.629	.12	.71	.541	.711
psy8	.914	.818	.984	.763	.185	.775	.584	.743

Correlation matrix of variables from interviews 1,4 and 8.

Correlation matrix

	Anx4	Dep4	Psy4	GI4	Sens4	Fat4	Sympt4	Phys4
GI8	.749	.704	.782	.99	.151	.654	.574	.782
Sens8	.222	.165	.223	.215	.991	.323	.386	.216
Fat8	.756	.7	.745	.643	.33	.998	.582	.649
Sympt8	.528	.601	.591	.599	.383	.579	1	.738
Phys8	.67	.768	.745	.779	.195	.668	.727	.994
Psycho8	.803	.831	.869	.774	.154	.741	.671	.805
Medint8	.383	.512	.271	.569	-.032	.325	.127	.393
Sex8	.214	.447	.381	.335	.126	.381	.584	.613
Global8	.764	.846	.82	.78	.166	.696	.754	.913
ERSS8	.619	.592	.638	.519	.262	.487	.75	.625

Correlation matrix

	Psycho4	Medint4	Sex4	Global4	ERSS4	anx8	dep8	psy8
Psycho4	1							
Medint4	.425	1						
Sex4	.491	-.023	1					
Global4	.907	.372	.623	1				
ERSS4	.76	.125	.742	.88	1			
anx8	.797	.44	.241	.751	.635	1		
dep8	.82	.491	.422	.797	.667	.823	1	
psy8	.885	.335	.398	.838	.758	.904	.829	1

Correlation matrix of variables from interviews 1,4 and 8.

Correlation matrix

	Psycho4	Medint4	Sex4	Global4	ERSS4	anx8	dep8	psy8
GI8	.789	.616	.346	.793	.603	.713	.678	.782
Sens8	.161	-.01	.106	.181	.381	.176	.125	.2
Fat8	.731	.332	.369	.67	.614	.768	.708	.779
Sympt8	.678	.127	.584	.779	.815	.508	.541	.584
Phys8	.812	.435	.623	.928	.808	.647	.753	.752
Psycho8	.998	.424	.49	.905	.757	.798	.828	.889
Medint8	.425	1	-.023	.372	.125	.44	.491	.335
Sex8	.491	-.023	1	.623	.742	.241	.422	.398
Global8	.907	.402	.624	.994	.866	.768	.831	.849
ERSS8	.722	.121	.501	.773	.813	.608	.551	.645

Correlation matrix

	GI8	Sens8	Fat8	Sympt8	Phys8	Psycho8	Medint8	Sex8
GI8	1							
Sens8	.188	1						
Fat8	.67	.342	1					
Sympt8	.574	.386	.582	1				
Phys8	.785	.204	.67	.727	1			
Psycho8	.79	.157	.738	.671	.815	1		
Medint8	.616	-.01	.332	.127	.435	.424	1	
Sex8	.346	.106	.369	.584	.623	.49	-.023	1
Global8	.796	.169	.694	.754	.927	.909	.402	.624
ERSS8	.503	.255	.483	.75	.618	.712	.121	.501

Correlation matrix

	Global8	ERSS8
Global8	1	
ERSS8	.753	1

Appendix C

Questionnaire to evaluate intervention by rehabilitation co-ordinator

The following questions are designed to find out how satisfied or dissatisfied you were with the service you received from Colette Fulton. Can you please listen to each question and answer each appropriately.

1. First I would like to ask you about the number of visits and telephone calls you received from Colette Fulton.
Do you think you received

More than enough?❑
Enough?❑
Not enough?❑

2. Did you receive information and advice from Colette on all the problems you wanted help with?
Would you say

None of the problems?❑
Some of the problems?❑
All of the problems?❑

3. Did you receive practical help from Colette with all the problems you wanted help with?
Would you say

None of the problems?❑
Some of the problems?❑
All of the problems?❑

4. Was the amount of practical help you received with those problems

More than enough?❑
Enough?❑
Not enough?❑

5. How helpful was the practical assistance you received?
Would you say

Not at all helpful ❐
Helpful ❐
Very helpful ❐

6. When you were provided with information or action was taken on your behalf, was the length of time taken to do this

Too quick? ❐
Just right? ❐
Too slow? ❐

7. Taking everything into consideration, how satisfied were you with the visits you received from Colette Fulton?
Would you say

Very satisfied ❐
Satisfied ❐
Dissatisfied ❐

8. Taking everything into consideration, do you think the visits you received made any difference to your life?

It made things worse ❐
It made no difference ❐
It made things better ❐

9. Please could you describe, in your own words, which aspects of the service you were most satisfied with? (For example:- Having someone to discuss problems with; having someone to give you advice etc.)

10. Please could you describe, in your own words, which aspects of the service you were least satisfied with? (For example:- the number of visits and phone calls or amount of help you received.)

11. If we offered the service to other people in the future, do you have any suggestions to improve it? Please describe.

Thank you so much for completing this questionnaire.